STATE OF MARYLAND
DEPARTMENT OF LICENSING AND REGULATION
DIVISION OF LABOR AND INDUSTRY

HEARINGS ON PROPOSED RULEMAKING BEFORE THE STATE OF MARYLAND, DIVISION OF LABOR AND INDUSTRY, RE: PROHIBITION OF SMOKING IN AN ENCLOSED WORKPLACE	:	Case No. 94-110-P

May 3, 1994
SPRING GROVE HOSPITAL CENTER
CATONSVILLE, MD.

BEFORE: HENRY J. KOELLEIN, JR., COMMISSIONER
ELAINE PATRICK, ESQ., COUNSEL
CAROLYN WEST, REGULATIONS COORDINATOR
ILEANA O'BRIEN, DEPUTY COMMISSIONER

REPORTED BY: BARBARA LORD

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PROCEEDINGS

(10:05 a.m.)

COMMISSIONER KOELLEIN: Good morning. I'm Henry Koellein, Jr., Commissioner of Labor and Industry. I will preside over today's hearing on COMAR 09.12.23, a proposed regulation to prohibit smoking in an enclosed workplace.

This regulation was recommended to me by the MOSH Advisory Board which composes, which is composed of representatives of industry, labor, the medical professions, the public and the agriculture. The Board, in making its recommendation, submitted a report with the record it has compiled.

The proposed regulation restricts smoking in the enclosed workplaces with the exception of separately ventilated rooms.

I would now like to call on Mrs. Carolyn West to read the Notice of Proposed Action as it appeared in the Maryland Register on April the 15th, 1994.

Ms. West?

MS. CAROLYN WEST: Commissioner, the

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Commissioner of Labor -- excuse me. The Commissioner of Labor and Industry proposes to adopt new Regulations .01-.05 under a new chapter, COMAR 09.12.23, "Prohibition on smoking in an enclosed workplace" as recommended by the Maryland Occupational Safety and Health (MOSH) Advisory Board. The new chapter is based on a recommendation to the Commissioner of Labor and Industry by the MOSH Advisory Board.

The MOSH advisory Board considered proposals on which these regulations are based at three public hearings held on January 12, 1994, February 2, 1994, and March 2, 1994. Notice of these meetings were given in Volume 20, Issue 25 of the Maryland Register on page 2003 on December 10th, 1993, and in Volume 21 Issue 4 of the Maryland Register on page 298 on February 18th, 1994.

The Board held two public hearings on the regulations on December 9th, 1993, and December 16th, 1993. Notice of these hearings was given in The Baltimore Sun on November 8, 1993, and in Volume 20 issue 24 of the Maryland Register on November 26th,

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1993.

Commissioner, in accordance with Labor and Employment Article Sections 2-106(B)(4) and 5-312, notice of this hearing was given in the Maryland Register, Volume 21, issue 8, on April 15th, 1994. In addition, a memorandum together with the Notice of Proposed Action and notice of this hearing were sent to the 94 individuals or associations on the Division's mailing list compiled from the individuals who either signed in at the MOSH Board hearing, called on this issue or expressed interest in this issue.

I would like to formally have a record of the proceedings before the MOSH Board marked into evidence. This includes Exhibits 1 through 96. We have also prepared an exhibit list which fully describes the additional material received at or since the MOSH Board hearing. Those have been listed as Exhibits number 97C through number 121C. I would present that exhibit list now.

COMMISSIONER KOELLEIN: They'll be received. Thank you.

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(The documents referred to as Commission Exhibits 1 through 121 were marked for identification and received into evidence.)

COMMISSIONER KOELLEIN: We'll start the testimony. In the interest of giving everyone an opportunity to participate please be brief and to the point, except for witnesses providing scientific or economic information. I will hold each witness to a maximum of five minutes.

For those who appeared before the Board please remember that I was there and don't need or desire repetition of the material already presented.

When you're called please come forward to the microphone, state your name, affiliation and address.

Mrs. West, will you please call the first witness?

MS. CAROLYN WEST: I call William A. Fogle, Junior, Secretary of the Department of Licensing and Regulation.

COMMISSIONER KOELLEIN: One moment, please.

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The Court Reporter, will you please swear in all persons who are going to testify today? All persons who are going to testify please stand.

(Whereupon, all witnesses were sworn.)

COMMISSIONER KOELLEIN: Thank you.

MR. WILLIAM FOGLE: Thank you, Commissioner Koellein. I know you recognize me but for the benefit of the court reporter I'm William A. Fogle, Jr., the Secretary of Licensing and Regulations for the State of Maryland.

As you know, Mr. Commissioner, a series of events led me to request that the MOSH Advisory Board look into the health and safety effects of smoking in the workplace. After extensive hearings and consideration of volumes of evidence the Board recommended a broad restriction of workplace smoking with my full support. After considering the Board's report you proposed the regulation at issue in this hearing.

This regulation restricts smoking in all enclosed workplaces to separately ventilated facilities

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or rooms.

You also know that over the past months I've banged the pulpit pretty hard on this particular issue, stating that the State of Maryland will prohibit workplace smoking. I'm sure you understand that by these remarks I am not directing you to adopt the regulation as proposed. You must make your judgement based on the evidence you receive and I have full confidence in your ability to evaluate that evidence fully and fairly. Rest assured, therefore, that you have my full support to reach the judgement to which the evidence points.

I also want to mention that three groups have contacted me on this matter. Between the time of the Board's recommendation and your Notice of Proposed Action the Baltimore Convention Center contacted me to express a desire to be included in the prohibition on smoking noting that their facility has been smoke free for years.

The Restaurant Association of Maryland contacted me twice to express their support for

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extending the prohibition to restaurants.

Finally, the Licensed Beverage Association contacted me to express opposition to including bars and taverns. Their concern was that such establishments would lose business to other nearby jurisdictions if they had to prohibit smoking. I responded by saying I believe that if this is true they would pick up non-smoker business from nearby jurisdictions and since non-smokers represent approximately 70 percent of the population this would be a positive not a negative. I also reminded them that this is a health issue and not a rights issue or an economic issue. The Association presented to me petitions signed by some 15,000 people objecting to the inclusion of bars and restaurants in the prohibition. I understand that these petitions have been presented this morning and are Exhibit number 113-C.

With that I will close my remarks. You have a full day and a big job ahead of you. I want to say be fair, which I know you will be, and good luck. Thank you very much.

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COMMISSIONER KOELLEIN: Thank you, Secretary Fogle. Our next witness?

MS. CAROLYN WEST: Dr. Walter Stewart.

DR. WALTER STEWART: Good morning, Commissioner. My name is Walter Stewart and I'm Associate Professor of Epidemiology at Johns Hopkins. 615 North Wolf Street, in Baltimore.

I'd like to take the next 20 minutes to review a risk assessment of the health effects of environmental tobacco smoke with regard to Maryland workers, and what I will do is to review the prevalence of exposure of ETS among workers, to describe a cumulative risk estimate of mortality from cardiovascular disease and lung cancer over a 45 year working lifetime, and then summarize with conclusions about whether or not environmental tobacco smoke poses a significant or substantial risk.

Let me just briefly -- you want -- just review what a standard risk assessment procedure is, and this follows really very much the procedures that would be used by EPA, OSHA and other regulatory

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agencies. There are several steps to process:

First, one needs to determine if an exposure poses a hazard, and I think that there is substantial evidence for that for environmental tobacco smoke.

The next step is to estimate the exposure prevalence in a relative population; in this case it's Maryland Workers, and then over a working lifetime to estimate the excess risk of mortality due to exposure.

And then, finally, the risk management decision is one where we have to judge whether or not the excess risk that we predict is acceptable or not.

So I will focus primarily on coronary artery disease risk denoted here by CAD, and use a rather large study by Helsing that was published in 1988 in the American Journal of Epidemiology. And that study is particularly relevant to this risk assessment because it was a study of Washington County Maryland residents. It is the largest study of environmental tobacco smoke ever conducted. The source of exposure is home exposure. It was a follow up study between 1963 and 1975; in that study Helsing showed a

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statistically significant increase risk in cardiovascular disease and mortality from environmental tobacco smoke, and showed a dose/response relationship which supports a causal association.

In that study overall, among those exposed to household ETS he showed a 31 percent excess risk of coronary artery disease mortality in men and a 24 percent excess in women.

Now let me just briefly describe how we use this study in estimating what the impact might be on Maryland workers. First we assume that the Helsing age specific rate of coronary artery disease and mortality are relevant to individuals during their working life; so in that study Helsing provided us with age specific rates of coronary artery disease. It was a study in Maryland, we assume that it's relevant to the Maryland working population. In order to estimate the impact of ETS we first estimate the risk of CAD mortality among individuals who are not exposed to ETS. We then estimate the risk of CAD mortality among individuals who are exposed to ETS. We take the difference in this

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risk and this tells us what the health impact is of ETS with regard to CAD mortality. And then we apply that estimate to the, to the estimated 60 percent of Maryland workers exposed to ETS.

Now in this next overhead which we'll have to do in sections, I apologize, what I show here is a set of age specific coronary artery disease death rates among men and women not exposed to ETS. This is from the Helsing study. And what you see, as expected, is that the age specific rate increases with age among both groups. If we took a hypothetical 1,000 individuals, so if we ask the question what is the cumulative effect, what is the cumulative incident of mortality among individuals not exposed to ETS over age that's shown in the right two columns. So we start with 1,000 hypothetical individuals, we apply the CAD mortality rate to those individuals and what we show among men is that from age 20 to 64 we would estimate that 185.8 individuals of 1,000 individuals would die from coronary artery disease mortality among men. Among women we would show that, we would estimate that

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88.4 out of 1,000 individuals would die of CAD mortality. Now this is among individuals not exposed, so this is what we would expect in the absence of ETS.

To use the Helsing study again there are age specific risks, CAD mortality risks among those exposed to ETS, we show in a, in the same fashion the age specific rates here, the effect on a hypothetical 1,000 individuals. And among men exposed to ETS we would expect 226, approximately 226 deaths per thousand and among women approximately 91.3 deaths per thousand.

So the next step in the risk assessment process is to take the difference in coronary artery disease mortality among those exposed to ETS and those not exposed, and the second line here we show that the excess risk that we might expect from ETS over a working lifetime, 20 to 45 years of age, is 37.7 deaths per thousand. So for a thousand individuals working in Maryland over their working lifetime exposed to environmental tobacco smoke this is what we would expect. Among women we would expect 2.9 deaths per thousand.

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Now, to get a combined estimate what we need to do is to weight these excess risks by a proportion of workers who are male and female in the population, and that's shown in this next line where we essentially multiply each risk by a fraction. And the overall excess risk that we would estimate is 21, approximately 21 deaths per 1,000 population, okay?

We can further modify that to taking into account the estimated proportion of working Marylanders who are exposed to ETS and if we applied that 60 percent factor we would estimate overall among working Marylanders we would expect approximately 12.6 deaths per 1,000 workers over a lifetime.

Now, let me just quickly review the assumptions in this risk assessment. First of all what I'd like to do is to review the assumptions and then go into each of them in a little more depth so that we understand what is behind these estimates.

First of all we assume that the risk of CAD mortality from environmental tobacco smoke is additive, and what we mean by that is that it adds risk to other

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risk factors. It doesn't interact in any way. We could have assumed that it was multiplicative but we assumed that it's additive. We assumed a linear dose response relationship and by that I mean that for each additional unit of exposure to ETS there is a linear increase in risk, not a non-linear.

We assumed in this risk assessment that environmental tobacco smoke at home is equivalent to that at work, and I'll talk briefly about that assumption and the consequences involved in that assumption. And in this model we did not assume that there was any effect of workplace ETS after retirement. I think probably there is but to simplify the estimates we assume that the, the health effects stopped after you left the workplace. All right?

Why use an additive model? It's a conservative estimate of excess risk, and by conservative I mean that it probably under estimates the risk if the actual effect is multiplicative, and I've described the contrast between additive and multiplicative. So if in fact what is going on here is

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that exposure to environmental tobacco smoke multiplies your risk and doesn't simply add to it then this would underestimate given the additive model.

And part of the reason for using the additive model is that the majority of Marylanders who are going to be exposed or who are exposed to ETS are non-smokers, and we worry about the kind of model only for the smoking population, so it's really a relevant model for the large percentage of workers who are exposed. And third, it's a, using an additive model simplifies the estimate of the excess risk, and that's one that's used frequently by OSHA, BPA, FDA and other regulatory agencies.

All right. Let me go a little more into depth on this, I will try to limit the quantitative aspects of this, but let me just contrast the additive model to the multiplicative model because these are the two models that we have to choose from. In order to use an additive model we first estimate the risk, the excess risk, it's first estimated among those with low risk of disease, in this case it's a non-smoker, non-

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smokers. What we then do is we assume that that same excess risk is added to the risk of smokers, okay? Not, we don't multiply it. Let me give you an example in this next overhead.

Let's assume that the excess risk of CAD mortality is, as I showed, 21.1 per 1,000. Okay? And let's assume that the risk of CAD mortality among smokers without workplace ETS exposure is 250 per thousand. Okay? What would be the additive effect of environmental tobacco smoke? Well, among non-smokers, let's say that mortality rate among non-smokers in the absence of ETS is 100 per thousand. We would simply add that 21.1 excess risk to the non-smoker risk and we would get an overall risk of 121.1 per thousand.

Among smokers we would do the same thing, we would simply add the risk to their existing risk, okay? And that's why we call it an additive effect.

So you can see here if we assume an additive model in this hypothetical example that the risk among smokers would be 271 per thousand of CAD mortality.

And the next overhead, if we used a

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multiplicative model the risk among non-smokers remains the same, the risk among smokers would be higher. Okay? I won't go into the details, I've submitted this part of all these overheads as evidence, but essentially this would, this, this overhead shows that if we used a multiplicative model we would actually get a higher risk of ETS and that justifies why it's a conservative model.

Let me just briefly discuss a linear versus a nonlinear model. I indicated that we used, we assumed a linear model. Ron, if you could just raise that up on the axis? The linear model is the straight line, the nonlinear model is the, obviously you can tell by the nonlinear line. And each of these lines show a hypothetical example of increase risk along the Y axis in relation to exposure. And what you can see is that at low risks, if the exposure were very very low, that the risk estimated from a linear model would be higher than that for a nonlinear, nonlinear model. If the exposure level of ETS were higher the risk estimated from a linear model would be lower than that of a

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nonlinear model. And it's not clear which of these models best applies; a reasonable assumption is to assume a linear model. Actually there's very little evidence to support one model over the other, so I think the model that we chose is perhaps reasonable.

Let me go to the third assumption which I think is particularly important. We assumed that exposure at home is equal to that at work, and we assumed that because Helsing looked at household exposure adn not workplace exposure. So if in fact this assumption is correct then the excess risk that we estimated of 21.1 per thousand is correct. If, on the other hand, workplace exposure is on average only half of household exposure, so if on average that's what somebody experiences in the workplace, then we would estimate an excess risk of CAD mortality of 10.5 per thousand. If we had an even more extreme assumption and we assume that a workers exposure was only 1/20th than that of household exposure -- for which there probably is little support -- then you would estimate an excess CAD mortality of approximately 1 per 1,000.

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Now, when you, there is also substantial evidence to indicate that environmental tobacco smoke is associated with an excess risk of lung cancer, there are many many more studies. I won't go into the laborious details of this, we did a risk assessment in very much the same way, there is an excess risk of lung cancer mortality but it's relatively small compared to cardiovascular disease mortality. The bulk of the excess risk is in cardiovascular disease mortality.

So let me just close with a few remarks, and let me just note that based on, you know, currently available studies and what I think are reasonable assumptions, we estimate a substantial excess risk of CAD mortality among Maryland workers.

COMMISSIONER KOELLEIN: Thank you, Doctor.

MS. ELAINE PATRICK: Dr. Stewart, I have a couple questions to ask you. This Helsing study, you relied on the Helsing study to get both the rates for the exposed and the unexposed?

DR. WALTER STEWART: That's correct.

MS. ELAINE PATRICK: That, now didn't they

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stop collecting the data on that study in the mid '70s? Or something?

DR. WALTER STEWART: Yes, there was a follow up study from 1960, the date, smoking status was obtained in the early '60s, the population was followed for 12 years up to 1975.

MS. ELAINE PATRICK: Now it's my understanding that coronary artery disease, the death rates have generally dropped since this period of time when Helsing quit collecting the data in that. Does that affect the analysis that you show?

DR. WALTER STEWART: Well, that goes to whether or not you assume an additive or multiplicative model. I think an additive model is probably more reasonable here and there's evidence to support that, and the evidence comes from other studies which show that when you compare individuals exposed to ETS to those not exposed there are other risk factors, cholesterol, blood pressure, weight, that are essentially the same. So I have assumed that the effect of ETS is additive and it doesn't interact with

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other risk factors.

Given that assumption and knowing that probably a large part of the reduction in cardiovascular disease mortality over the last decade has been due to reducing other risk factors the risk from ETS still remains. So it is still additive, it adds to the risk whether or not it decreases because of a decrease in other risk factors.

MS. ELAINE PATRICK: So then as the other risk factors decline in significance the ETS remains stable?

DR. WALTER STEWART: As long as ETS exposure remains where it is the risk associated with it, the excess risk will remain the same is what I would assume. And we know that other risk factors have declined substantially, fat intake, weight, blood pressure. We've been effective in making inroads into those risk factors.

MS. ELAINE PATRICK: And do I understand these numbers, 20 per thousand, that's about 2 percent?

DR. WALTER STEWART: Pardon?

MS. ELAINE PATRICK: That's about 2 percent, 20

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per thousand, about 2 percent?

DR. WALTER STEWART: That's correct.

MS. ELAINE PATRICK: And that's that you increase, that, that means the working person in America has a 2 percent greater risk over my lifetime --

DR. WALTER STEWART: Over your working lifetime.

MS. ELAINE PATRICK: Over my working lifetime of coronary artery disease death as a result of ETS exposure?

DR. WALTER STEWART: That's correct.

MS. ELAINE PATRICK: All right. Now I've seen some statistics on overall coronary artery disease death rates which suggest they're like, for Maryland like 250 per 100,000. I don't, I don't understand. Seems to me we're getting more deaths from ETS than we're getting overall.

DR. WALTER STEWART: Right. I, that sounds like an annual risk, what you're quoting, and not a lifetime risk.

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MS. ELAINE PATRICK: I think it is.

DR. WALTER STEWART: If you applied the same risk assessment methodology as we did here you would estimate, you know, given the Maryland population, a overall risk of CAD mortality between 20 and 65 years of age of around 10 to 20 percent, depending upon your weight, blood pressure, things of that sort.

MS. ELAINE PATRICK: Uh-huh.

DR. WALTER STEWART: So a 15 percent mortality rate probably is a reasonable estimate for their working lifetime.

MS. ELAINE PATRICK: So then you still haven't given us the annual rate, that shows around 250 per 100,000, and when you project that out over 45 years that would be more along the line as to what you're showing us here today?

DR. WALTER STEWART: Precisely.

MS. ELAINE PATRICK: All right.

COMMISSIONER KOELLEIN: Thank you.

DR. WALTER STEWART: Thank you.

MS. CAROLYN WEST: Thank you, Dr. Stewart. I

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would like to note that the statement of Secretary Fogle has been entered in as Exhibit number 122, and the materials submitted by Dr. Stewart have been entered in as Exhibit number 123.

(The documents referred to as Exhibits 122 and 123 were marked for identification and received into evidence.)

COMMISSIONER KOELLEIN: Thank you.

MS. CAROLYN WEST: Let's call now on Larry Johnson.

COMMISSIONER KOELLEIN: Before we proceed I would like to introduce the lady to my right. She is Elaine Patrick, she is my legal counsel from the Attorney General's Office.

MR. LARRY JOHNSON: Good morning, Commissioner. My name is Larry Johnson, I'm a certified industrial hygienist. I'm here today representing the American Industrial Hygiene Association.

Late last year the American Industrial

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Hygiene Association joined with two other professional organizations, the American Association of Occupational Health Nurses and the American College of Occupational and Environmental Medicine. We formed a coalition that developed a position paper that we submitted to the Occupational Safety and Health Administration, and I would like to read excerpts of that position paper that I feel are pertinent to the proceedings today.

Occupational health professionals focused on health promotion and disease prevention for American Workers. In light of the compelling evidence about detrimental health effects the Coalition, comprised of health nurses, occupational medicine physicians and other physicians and industrial hygienists, believes that workers should not be exposed to environmental tobacco smoke. The risk of developing cancer or other health problems in workplace exposure to ETS should be minimized. Clearly many employers, employees, health professionals and others are concerned about this issue. The Occupational Safety and Health Administration received more than 1200 responses to a

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September 1991 request for information on occupational exposure to indoor air pollutants. More than half of these responses addressed smoking in the workplace.

Following the industrial hygienist's hierarchy for controlling hazards in the workplace the best method is to eliminate the hazard; in this case to ban smoking in the workplace. Employers will, in most cases, find this the easiest and least expensive method for controlling workplace exposure to environmental tobacco smoke. To facilitate elimination of smoking in the workplace employers should take a comprehensive health promotion disease prevention perspective. This requires a written policy developed in collaboration with employees, labor, management and health professionals.

The policy should: Apply to all workers at the location; be clearly communicated to all employees well in advance of implementation; have a phased in implementation period; provide incentives for smoking cessation and penalties for not adhering to the prohibition on smoking; and be clearly communicated to

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all visitors entering the workplace.

Smoking cessation programs should be offered in advance of policy implementation in an ongoing basis. Successful approaches include but are not limited to: Programs that address the different components of smoking addiction; follow up programs for potential relapse; on site and off site locations for programs; ongoing programs available to employees and their families offered at various times; reimbursement for prescription devices if they are needed; on site or consultant occupational health professionals and/or employee assistance professionals for education and counseling support to deal with psychosocial aspects of smoking cessation.

If elimination is not possible then engineering controls must be implemented to protect non-smokers. Designated smoking areas must be designed to prevent ETS contamination of other areas in the work environment. Employers should: Designate separate enclosed areas for smoking with separate ventilation; air from these areas should be exhausted directly

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outside and not recirculated within the building or mixed with general with pollution ventilation for the building. Smoking rooms should meet general ventilation standards and the smoking area should have a slight negative pressure to ensure air flow into the area rather than back into the air space of the workplace. In accordance with the American Society of Heating, Refrigerating and Air Conditioning Engineers Ventilation Standard 62/1989.

Visual clues should be posted and warning signs posted at entrances to the workplace in English and other predominant languages of non English reading workers stating that smoking is permitted only in designated areas. Clearly identify designated non-smoking and smoking areas by signs and appropriate symbols.

We also recommend monitoring for exposure based upon a measurement in air of appropriate component of environmental tobacco smoke.

In summary, the Coalition supports regulation of environmental tobacco smoke in the workplace to

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promote and preserve the health of American workers. The harmful effects of exposure to ETS are clear. The Coalition calls upon other organizations and individuals representing employees, business and industry and other health professionals to join in this important effort. We offer our technical expertise in controlling workplace hazards to the Department and all other parties interested. Thank you.

COMMISSIONER KOELLEIN: Thank you, sir.

MS. CAROLYN WEST: Dr. Rex Archer.

DR. REX ARCHER: My name is Dr. Rex Archer and I'm here wearing several hats --

COMMISSIONER KOELLEIN: Nice to see you again.

DR. REX ARCHER: -- couple of state hats in regards to the Maryland Association of County Health Officials, representing them, and the Maryland Advisory Council on High Blood Pressure and Cardiovascular Disease, on cardiovascular related risk factors. I also wear a county hat as the Health Officer for Garrett County and in representing our tobacco free

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coalition for the county that has over a dozen organizations and members.

My main purpose since the last hearing was to review for the Maryland Association of County Health Officials evidence on environmental tobacco smoke and cardiovascular disease as well as to report to you that the scientific committee for the Advisory Council on High Blood Pressure and other cardiovascular disease which is, made recommendations to the overall Council has concluded that environmental tobacco smoke is a primary risk factor for cardiovascular disease in non-smokers.

Another point that I do want to make is regardless of your decision in regards to the weight of the evidence on cardiovascular disease there is already clear scientific consensus with a number of groups on the lung cancer risk, and looking at those risk models there is certainly too many deaths already occurring to ignore that, even if you don't add in the additional risk of cardiovascular disease. We've looked at this issue in our county and on an average we'll lose about

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one person each year to cancer and another three to four to heart disease due to exposure to other people's tobacco smoke if you just adjust down the numbers from the state or the national levels.

I'd also like to point out when you're weighing the evidence and looking at other individuals that have testified or submitted evidence that if it comes from the tobacco industry it is very suspect; they've already been caught presenting misinformation in numerous situations and I would like to submit a copy of a letter from the American Medical Association published in their journal back in November of '91 which discusses their analysis of a environmental tobacco smoke, a review of the literature from the Tobacco Institute of New Zealand that has been used and submitted a number of places. This examples is back in Kansas, and they found that 75 of the 331 references couldn't even be found including a whole book, so the conclusion to this letter is that pro-health groups should be aware of these employees and scrutinize third party efforts to pose tobacco control actions,

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potential involvement of the tobacco industry. It's fairly clear what their reasons for being involved are.

I'd really like to then close with -- and as I was looking at the evidence that's already presented and I'm not sure that I'll get this exactly right, I'll be paraphrasing Martin Luther King: "Morality cannot be legislated but behavior can be regulated. Regulations may not always change the heart but they can restrain the heartless."

And I think that's really what this is about, so either the tobacco industry which has already proven that it's heartless, or the merchants that are either ignorant or they're aware of what they're doing to their workers and their patrons by exposing them to smoke are clearly heartless, individuals that are addicted to nicotine while they're still addicted and are in that problem phase of their life are certainly heartless when they expose other people to environmental tobacco smoke, and it's the responsibility of government to deal with them. Thank you.

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MS. ELAINE PATRICK: Dr. Archer, before you leave I just wanted to -- is that for me? I wanted to clarify a couple of things that you said, that there was a scientific advisory council that I'm -- Who is that group or what is that group?

DR. REX ARCHER: The Maryland Advisory Council on High Blood Pressure and Related Cardiovascular Risk Factors.

MS. ELAINE PATRICK: You have a book down there, is that something for the record or --

DR. REX ARCHER: Yeah, this is still a draft phase. We are meeting on the 20th to hopefully finalize our plan to be submitted, similar to the Cancer Council's plan, an action plan, but it's still in draft form so I would not be submitting it at this time. But a scientific committee has made those conclusions and has recommended it to the overall council; the council has not met to discuss those yet.

MS. ELAINE PATRICK: And it's a state --

DR. REX ARCHER: Yes.

MS. ELAINE PATRICK: -- appointed by the

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governor?

DR. REX ARCHER: By the governor, yes.

MS. ELAINE PATRICK: And it includes representatives from the --

DR. REX ARCHER: It's listed in, the scientific advisory committee is Dr. David Levine, Dr. Dan Ford, Dr. Roger Sherwin, Dr. Szklo -- sorry about the pronunciation.

MS. ELAINE PATRICK: You can spell it for the court reporter, she's looking at me already.

DR. REX ARCHER: Well, I'll just hand this over to her --

MS. ELAINE PATRICK: Okay.

DR. REX ARCHER: -- give that to the Committee, and Dr. Paul Wilcom, and --

MS. ELAINE PATRICK: So then the scientific advisory, that panel has reviewed --

DR. REX ARCHER: Reviewed the evidence on environmental tobacco smoke --

MS. ELAINE PATRICK: And are making a recommendation that it be --

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DR. REX ARCHER: It will be listed in the report, assuming that the council includes it and they usually do, the overall council usually does approve what the scientific committee recommends to them in regards to the scientific evidence. And so they will be, I'm assuming that, you know, it's not there yet, on the 20th. But the committee has, the scientific committee has clearly stated that environmental tobacco smoke is a primary risk factor for heart disease in non-smokers.

MS. ELAINE PATRICK: Now what does "Primary" mean? Are there secondary risk factors?

DR. REX ARCHER: Well, a primary major risk factor.

MS. ELAINE PATRICK: Major?

DR. REX ARCHER: Similar to what the American Heart Association's Scientific Council determined. When you look at a range of 30 to 40,000 deaths in a year on an annual basis across the whole US, I would consider that a primary major risk factor in regards to the number of deaths.

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MS. CAROLYN WEST: Thank you. Commissioner, I would put a letter submitted by Dr. Archer as Exhibit number 124.

COMMISSIONER KOELLEIN: Thank you.

(The document referred to as Exhibit 124 was marked for identification and received into evidence.)

MS. CAROLYN WEST: I would call Kathleen Scheg and Peter Meyers.

MS. KATHLEEN SCHEG: Mr. Commissioner, for the record my name is Kathleen Scheg, I'm representing Action on Smoking and Health, and I'm also a Maryland resident concerned from that perspective.

I would like to begin by commending you for proposing workplace smoking regulations for Marylanders. These regulations are extremely important for environmental tobacco smoke is the greatest occupational health hazard facing Maryland workers today. In support of those regulations today I would like to offer the following information regarding the

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economic feasibility of including restaurants.

First I would like to submit the Glantz and Smith studies on the effect on restaurant sales on the ordinances requiring smoke free restaurants. Second I'll submit that the large number of jurisdictions which have already passed smoke free ordinances demonstrates the economic feasibility of doing so. Third I propose that anecdotal evidence also supports inclusion of restaurants in Maryland's prohibition on smoking in the workplace.

First the economic studies. The only known long term studies analyzing the economic impact on restaurant revenue of ordinances requiring smoke free restaurants are the four studies conducted by Stan Glantz and Lisa Smith, and at least two of those reports were clearly released after the MOSH Board hearings. In each of the four studies data was obtained from the independent objective government bodies responsible for gathering sales tax data; namely the California State Board of Equalization and the Colorado Department of Revenue. These are the two

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states whose 15 cities had 100 percent smoke free restaurant ordinances in effect long enough to analyze whether there was any economic impact. All four studies showed the presence of a higher percent smoke free restaurant ordinance had no significant effect on the total restaurant sales in any community. The presence of 100 percent smoke free restaurant ordinance had no significant effect on the ratio of restaurant sales in communities with such an ordinance compared with matched control communities which had no such ordinance.

The March '93 study is significant because it is the first multistate analysis of taxable sales from the first 13 US cities to enact smoke free restaurant ordinances. In the January 1994 update Sacramento and Martinez were added. Sacramento is particularly important because it is a major city and the capital of California. Significantly, Glantz and Smith also compared restaurant revenues in Sacramento City and surrounding Sacramento County and found no effect from the Sacramento City ordinance on restaurant revenues.

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The February 1994 report further noted that the 15 city study represented a broad cross section of jurisdictions that might enact smoking control measures. Included among others were a large city, a well to do urban city, a middle class bedroom, a rural agricultural community, an industrial area and three resort towns. There was no adverse restaurant business impact in any of these communities, thereby prompting a conclusion that the results generalized broaden.

In addition to the formal studies showing no adverse economic impact on restaurants in jurisdictions with smoke free ordinances evidence of economic feasibility is demonstrated by the growing number of jurisdictions that have enacted such policies. ASH has identified over 100 jurisdictions that have enacted smoke free restaurant policies. All of these jurisdictions rejected the tobacco industry's unsubstantiated claims of potential loss revenue and Maryland should do likewise. Maryland can take notice of the growing body of experiential information and proceed to protect the health of its restaurant

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employees.

Anecdotal evidence also documents that smoke free restaurants are economically feasible; the growing number of individual restaurants as well as large restaurant chains that have gone smoke free further reinforce the economic feasibility. The national press has carried the news such as major chains such as McDonald's, Arby's, Dairy Queen and Chuck-E-Cheese banning smoking in the restaurants they own. McDonald's alone has more than 3600 smoke free restaurants. Additionally, numerous individual restaurants of all types and size have joined the smoke free restaurant movement on their own initiative.

To state the obvious these are all business people who have made these decisions to go smoke free. They would not have done so if they believed there would be an adverse economic impact for that would clearly be against their economic interest.

In conclusion, there is ample evidence for including restaurants in Maryland's prohibition on smoking in the enclosed workplace. The only long term

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objectively based studies by Glantz and Smith consistently found that smoke free restaurant ordinances have no significant impact on restaurant sales. The proliferation of jurisdictions enacting smoke free ordinances, including state-wide bans in Utah and Vermont which go into effect in 1995, show that other government bodies who have examined this issue also believe there will be no adverse impact on their communities. Third, the numerous individual restaurants and chains that have voluntarily gone smoke free demonstrate that those who would be most concerned about the impact of going smoke free have decided that it is feasible to do so.

Finally, I again commend you, Commissioner, and the other Maryland officials who have participated in the decision to propose regulations prohibiting smoking in enclosed workplaces in Maryland. We particularly applaud your decision to include restaurants in the proposed regulations and urge you to keep them in the final regulations. Thank you.

COMMISSIONER KOELLEIN: Thank you.

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MR. PETER MEYERS: Good morning, my name is Peter Meyers and I am adjunct professor of law at the George Washington University Law School where I teach a course on substance abuse, including tobacco products, and I am also special counsel to ASH.

I'd like to address two points this morning if I could. First I'd like to talk about the real sea change that has happened in the months that this Agency has been considering banning smoking in Maryland, and second to also talk about, in addition to what Ms. Scheg pointed out, that there isn't going to be a substantial economic impact if smoking in restaurants and bars is allowed to go through. More than that, even if there was some financial impact the Maryland OSHA law requires this Agency to have an across the board ban and it would not allow a specific exemption for restaurants and bars.

First, the sea change. I can remember testifying before the Advisory Committee last year in support of this regulation and at that point it seemed that Maryland was way out front; it was out there well

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before what other governmental bodies and institutions were doing. Today as we sit here it's apparent that there has been a major major change in the regulation of environmental tobacco smoke in this country and that Maryland is no longer way out front but is really part of the mainstream. In addition to what Ms. Scheg has pointed out about all the fast food restaurants and states such as Utah and Washington which have passed smoke free laws, we have institutions such as the military where today as a result of action smoking is prohibited in all military workplaces. Smoking is prohibited now in schools. There are a whole variety of areas where governments and private individuals and organizations have acted to protect the health of persons from environmental tobacco smoke. And perhaps the most important change is that the federal OSHA has now proposed regulations which would restrict smoking in all workplaces throughout the United States.

When, I can remember when we were at the Advisory Board hearing and we were discussing what was happening on the federal level the representatives and

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the lawyers for the tobacco industry stated that there's no need for this agency to act because the federal government has already begun to act. Well at that time it was a misrepresentation, as much of what the tobacco representative said it was not true, the federal government had not acted at that time. However, between that hearing and today the federal government has proposed regulations. And I think with respect to what this state is doing there are three most important things about what the federal government is proposing to do:

First of all, the regulation itself is very similar to the Maryland regulation, it bans smoking across the board but it allows for an exception for separately ventilated rooms with negative pressure. Very similar to what is proposed in Maryland;

Second, there is no exemption for certain workplaces such as restaurants and bars, all these establishments are included and it desires to protect the workers in all these places not with certain restrictions and limitations;

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Third, and I think also perhaps most important, while the federal government has begun the process, has proposed regulations, it is going to be a long time before these regulations actually take effect. One federal OSHA official has been quoted in the industry press, a spokesman, as saying that it may take as long as five to eight years before the federal regulation is finalized. I don't know and I don't know whether anybody can tell you for sure how long it'll take, but it's going to be a very lengthy process, it is a complex proceeding, much more complicated and involved than this proposal and it is going to take a substantial amount of time before that becomes final. And it seems to me that it is another argument for the fact of not waiting until that's finalized, but to give the workers of this state the protection as they are being protected in Washington, Utah and other states, to give them this protection as soon as possible without waiting for the federal government to finalize their nationwide regulations.

Second, Ms. Scheg pointed out that the

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studies to date show that there will not be a substantial economic impact in terms of restaurants if smoking is prohibited or again restricted to separately ventilated sections. I want to also point out from a legal perspective that even if there was some economic impact, even if some restaurants would lose some money the law requires it, the ban to be across the board and that many regulations, federal and state, require substantial financial resources and that is not a reason not to require that regulation. This is gone into in detail in my written statement and I, I hear my time is up so instead of discussing that I will just submit my written statement on the legal analysis that you cannot exempt bars and restaurants under your own state law.

COMMISSIONER KOELLEIN: Thank you. Any questions? Thank you both.

(Brief off the record discussion.)

MS. CAROLYN WEST: Commissioner, I note that the testimony provided by Kathleen Scheg is introduced as Exhibit number 125, the testimony provided by Mr.

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Meyers is entered into evidence as 126.

(The documents referred to as Exhibits 125 and 126 were marked for identification and received into evidence.)

MS. CAROLYN WEST: I now call on Dr. Francis Stillman.

COMMISSIONER KOELLEIN: Thank you. Welcome, Doctor.

DR. FRANCIS STILLMAN: Thank you. As I presented before the MOSH hearing I'll be very brief. I just wanted to add a few things.

My name is Dr. Francis Stillman, I'm assistant professor at the Johns Hopkins University School of Medicine in the department of internal medicine. At the Center for Health Promotions at the earlier hearing I presented on our evaluation study that was published in JAMA, and I presented that into the evidence, where we had provided, implemented a smoke free hospital in 1988 and then evaluated that policy a year later and looking at changes in the

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workplace. Somebody previous, one of the speakers, had introduced a model of that basic property, the best model, policies we basically had developed, such a model where we had health promotion activities, smoking cessation, we also monitored environmental tobacco smoke in the atmosphere, we had observations in many areas of the hospitals looking for smoking and also collecting smoking remnants to determine the changes that would occur in the institution from implementing such a policy to afterwards. We also surveyed over 10,000 of our employees, as the hospital is one of the largest employers in the State of Maryland to look at attitudes.

I had previously presented the fact that at the, at the year evaluation we noted that the smoking prevalence had dropped in our work force, we also found that the number of cigarettes reported smoked by people who still continued to smoke was decreased, and incidentally we had a number of fire incidents, averaged four years before that of about 20 per her at the hospital, during that year following at the

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hospital there were no fire reports. But we also found that environmental tobacco smoke, we used atmospheric nicotine monitors to measure this, fell by three fold in almost every area of the hospital. We looked at waiting rooms, we looked at cafeterias, we looked at patient areas, staff lounges and elevator lobbies and, you know, the only place it did not fall was in the rest room; it fell, but it was not a significant level. There was an 80 percent decrease in the rest rooms but it was not a significant level.

One of the things that I had not mentioned in a previous committee hearing was the fact that we have another study out that looked at 1,000 nurses and about 800 physicians. We looked at their attitudes before the survey went into effect and then we looked at their behaviors a year later, and their negative attitudes -- and there were negative attitudes -- in the work force concerning the implementation of the policy did not affect their behavior, so that people even with negative attitudes went on to quit smoking which we, the reason why we implemented such a policy is that we

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felt that a medical institution needed to be in the forefront of protecting the health and welfare of its employees and its patients and visitors, and we found that our policy not only cleared the atmosphere of environmental tobacco smoke in almost every area of the institution, but it also effected behavioral change, and the negative attitudes before did not effect the behavior after.

I also had people give comments, we collected close to 5,000 comments and again I think the Commission should realize that the majority of the people in the State of Maryland and across the United States are non-smokers, and I went through every single one of these comments, I have stacks of them. The stacks are complaints about what the policy did, were minimal. Most of them, 90 percent, were in favor of the policy and wanted it actually moved from the doorways, which we've gone on to move it actually from the outside areas and move it into designated areas outside the facility.

The other -- and that was not in my report,

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anecdotal report about what happened in the cafeterias in the institution, we're a large institution, we have many cafeterias. And there was a, a slight decrease in revenue in those facilities during the year following the implementation of the ban. It may have something to do with the food, I don't know, but when I went back a year later the revenues were back up to their original, and actually I was told they began to exceed what they had done the year before. So there was a minimal effect on the business; however, in our institution some of the buildings across, like the School of Public Health was not free. The hospital was smoke free, so there was a cafeteria in the School of Public Health, so the following year we went and created a smoke free environment in the School of Public Health, then we went to the School of Medicine, and we eventually made the entire institution smoke free and I think that basically meant that people needed to leave the institution and go to restaurants, but even after that was created the revenues maintained at their normal levels within the cafeterias in our

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institution, even though people had choice in the community to go out for their meals.

So I, I basically commend the Commission. We found at Hopkins that this policy was extremely effective. We cleared the air, as we said, two to three folds on environmental tobacco smoke exposure of our employees, we've gone on to measure compliance which was excellent, and also now we have a paper that will be going out on compliance of our patients who are basically captive, and that compliance is also very excellent, so we think that these policies are extremely effective, and think that these should be in every workplace in the State of Maryland to protect the health and welfare of all our citizens.

Thank you very much.

COMMISSIONER KOELLEIN: Thank you, Doctor.

MS. CAROLYN WEST: I call on James D. Gilpatrick.

MR. JAMES GILPATRICK: Good morning, Commissioner. My name is James Gilpatrick, I am the owner and operator of the Rolling Road Tobacco

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Warehouse which is a tobacco shop in Lutherville, Maryland. I have a prepared statement and I respectfully ask -- it runs a few more than five minutes and I ask your permission to be able to read this statement in total, should be in seven or eight minutes.

COMMISSIONER KOELLEIN: Let's give it a try.

MR. JAMES GILPATRICK: Thank you, sir. Thank you, Commissioner, for allowing me to testify at this hearing, and for the opportunity to help represent the tobacco side of the volatile issue of ETS and its effects on non-smokers.

I have probably worked in the tobacco industry for the last 31 years. John Stossel, a distinguished consumer advocate reporter for ABC-TV recently aired a program entitled "Are we scaring ourselves to death." His program explored and uncovered many scare tactics regarding issues that have been released both, by both special interest groups and our own government. Unfortunately he left out one of the current health issues, environmental tobacco smoke,

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that not only would have met the criterion for inclusion in this program's content, it would have exceeded them by at least a mile or two.

In 1962 the federal government released its first report on smoking and health in an attempt to intrude on people's lives by scaring them into believing that if they did not quit smoking they would all surely die before their time. Well, millions of Americans read the data and the statistics, formed their own opinion and continued their moderate and enjoyable use of this legal product.

Well, said the government, they aren't doing what we said so let's make it tougher. Let's increase taxes, put warning labels on packages and limit their smoking opportunities. That didn't seem to work either. These foolish smokers are still enjoying themselves. Now, suddenly, after almost 30 years of research the antismoking forces think they have found their "This will get them for sure" issue, environmental tobacco smoke, and have been issuing a steady stream of statistical evidence to prove their

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point.

Commissioner, if you have studied the information carefully you must come to the conclusion that the issue of the deleterious effects of ETS has yet to be proved conclusively and regulations such as 9.12.23, prohibition on smoking in the enclosed workplace, are not only unnecessary but a dangerous precedent to the potential power that government, federal or state, could impose on our daily lives.

To prove my point let's start with some standard reported statistics. How many smokers die each year from smoking? Is it 300,000? 450,000? 500,000 or more? These are numbers I have seen in print that are reported in the electronic media, but which is true? After all, aren't we all reading the same data released by HHS or the Surgeon General? How about this one, how many people die each year from inhaling ETS? Your statement of purpose says the number is 14,000, yet in a recent article in U.S. News and World Report the annual number was only 9,000, and the EPA study lists additional deaths at 3,000. Then

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we have the reported statistic that states for every cigarette we smoke we lose 12 seconds off our lives. If you calculate that number times a pack a day, 20 cigarettes, and extend it for a smoker starting at the legal age of 18 and continuing for 50 years we would lose, according to their statistics, approximately 50 days off our life expectancy. 50 days.

At the end of John Stossel's program the other night he showed a list of potential life expectancy loss for some of our government and media generated health scares. Down near the bottom of that list was smoking deaths which was given an expectancy loss of 5 and a half years with no supporting data given for that statistic. A discrepancy of over five years.

I would like to read some excerpts from a recent article that appeared in the Wall Street Journal written by Dr. -- Mr., I'm sorry, Mr. Jacob Sullivan who is the managing editor for Reason Magazine.

"Many supporters of such measures probably believe that the EPA report represents definitive

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scientific evidence that exposure to ETS causes lung cancer, but those who have taken a closer look have come to believe that the EPA twisted the evidence to arrive at a predetermined conclusion. The overriding motive was to discourage smoking by making it less acceptable and more inconvenient. Yet coercing people for their own good still raises a few hackles in this country so paternalists needed to offer some additional justification; that's why they've been pushing the idea that smoking endangers innocent bystanders. The problem is the evidence for this claim is weak, inconsistent and ambiguous. The EPA's report seems designed to conceal that problem. Analysts generally call an association between a risk factor and a disease significant if the probability of that occurred purely by chance is 5 percent or less; this is also the standard that the EPA had always used for risk assessment. Yet for the report on ETS the Agency abandoned the usual definition and called a result significant if the probability that it occurred by chance was 10 percent or less. That change in effect

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doubles the odds of being wrong. Even according to the broader definition only one of the 11 US studies that the report analyzes found a statistically significant link between ETS and lung cancer. According to the usual definition none of them did."

In 1991 Gary Huber, Professor of Medicine at the University of Texas Health Center, and two colleagues examined the 30 ETS studies discussed by the EPA in it's report. At least 20 confounding variables have been identified as important to the development of lung cancer they wrote in Consumer's Research. "No reported study comes anywhere close to controlling or even mentioning half of these. The EPA also assumed that lung cancer risk is directly proportional to ETS levels and that no level of ETS can be considered safe, yet dose/response relationships vary from one substance to another and many scientists believe that a carcinogen has to be present at a certain level before it can do any harm. Given these and other contrivances employed by the EPA it is difficult to avoid the conclusion that policy has dictated science in the case

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of ETS. This approach may be politically effective in the short term but it is ultimately self defeating. By compromising the standards and methods of science the experts also undermine their claim to authority."

And that, Commissioner, is my point, Environmental tobacco smoke is and has always been a matter of social acceptance and should be treated as a, such. Courtesy, common sense, moderation and market forces should dictate smoking policies in stores, malls, corporations, restaurants, lounges or offices and the privacy of your own home, not more laws or regulations that force more social shackles on the general public at the whim of a few.

Thank you for your time and attention.

COMMISSIONER KOELLEIN: Thank you, sir.

MS. CAROLYN WEST: Let me say that Mr. Gilpatrick's testimony is Exhibit 127.

(The document referred to as Exhibit 127 was marked for identification and received into evidence.)

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MS. CAROLYN WEST: Call on H. Selby Scaggs.

MR. H. SELBY SCAGGS: Good morning, my name is H. Selby Scaggs Jr., I'm a restaurant owner in Montgomery County and I'm here today in strong opposition to any proposed regulation banning smoking from public places in the State of Maryland.

Understanding your concerns about the health and safety of employees I want to assure you that I am equally concerned; however, their total welfare is the most important consideration to me. Health and safety can be guarded by the loss of jobs cannot. At the present time 11 to 14 percent of my business comes from the District of Columbia and Northern Virginia; approximately 7 to 12 miles away from my location. Excuse me. With the imposition of a new regulation under consideration now not only would we lose incoming business but the present local patrons would have but a short distance to be able to exercise their own freedom of choice. This would also be true to other areas that were in adjoining states. With a loss of business to these other unregulated areas will come a loss of jobs.

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You must consider the effect of these regulations on all areas of the state, not just the central locations. We have many close neighbors who are not restricting the freedom of choice. Some restaurants in Montgomery County have chosen to become totally smoke free and that is their freedom of choice. There is a new, these new regulations will take away my freedom of choice as a businessman and drive my smoking customers away. My customers should be allowed by their patronage to tell me, to tell me what their smoking choice will be as they have told me in the past what their food choices would be.

The present laws in Montgomery County have allowed choice in smoking and non-smoking areas for the past four years. This arrangement has worked well for all concerned. The new regulations as proposed will allow for a smoking area for employees, but I will not be allowed to offer this choice to my customers.

I ask you please, no more additional government regulations. The public is intelligent enough to decide what they want by their own choice,

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they do not need the state to decide for them. Thank you.

COMMISSIONER KOELLEIN: Thank you.

MS. ELAINE PATRICK: I wonder if you all are going to applaud for me. Mr. Scaggs, you said some of the restaurants in Montgomery County had gone smoke free voluntarily?

MR. H. SELBY SCAGGS: Yes, that was, they -- I don't know the exact number, but there are --

MS. ELAINE PATRICK: And are you familiar with any of the owners of those establishments?

MR. H. SELBY SCAGGS: Yes.

MS. ELAINE PATRICK: And have they noticed a big decline in their business?

MR. H. SELBY SCAGGS: I haven't talked to them. I haven't noticed to be honest with you. I couldn't give you a straight answer on that. But that's their choice, they did it --

MS. ELAINE PATRICK: I understand.

MR. H. SELBY SCAGGS: If the public demands me to do it, of course I'm not going to lose business

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if that's what they say they want, then that's what they're going to get.

MS. ELAINE PATRICK: Uh-huh. But as far as you know those, those who have converted to a smoke free, but as far as you know you just don't know what the impact on their business has --

MR. H. SELBY SCAGGS: No, it hasn't, I would imagine it's only been six months that most of them have done that. When I say most of them I know it was three in a certain area.

MS. ELAINE PATRICK: But you're, Anchor Inn, where is that?

MR. H. SELBY SCAGGS: Wheaton.

MS. ELAINE PATRICK: In Wheaton?

MR. H. SELBY SCAGGS: Uh-huh.

MS. ELAINE PATRICK: Thank you.

MR. H. SELBY SCAGGS: Thank you.

MS. ELAINE PATRICK: See, I knew you wouldn't applaud for me.

MS. CAROLYN WEST: I call Brendan Flanagan.

MR. BRENDAN FLANAGAN: Good morning,

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Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

Commissioner Koellein. I am Brendan Flanagan and I represent the Restaurant Association of Maryland, and the three gentlemen accompanying me are restaurateurs from various parts of the state, and after I present to you the Association's position on this issue then they'll be more than happy to provide you their insights on the issue.

The Restaurant Association's position on smoking is simple and consistent. We oppose any regulation or legislation which singles out restaurants for discriminatory treatment or which threatens to put them at a competitive disadvantage. Currently this regulatory proposal is state-wide and applies to all business equally; therefore RAM supports this regulatory proposal as it presently exists. If, however, there are any amendments which grant any exclusions we will then have to reevaluate our position.

It is our fear that in the absence of state-wide or all inclusive proposals that we will be faced with a mixture of county specific or municipality

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

specific attempts to ban smoking and that many of these would apply to just restaurants and not bars, taverns and private clubs which compete daily with restaurants for business. That's why we support this effort, because it is state wide and it provides us all with a level playing field upon which we can compete fairly.

We are not scientists, but those who are say that second hand smoke presents a health hazard. If this is true then employees are entitled to a safe workplace, and if some employees are entitled to a safe workplace then all employees are entitled to a safe workplace. Once it is determined that it is necessary to protect employees from the hazards of environmental tobacco smoke there can be absolutely no justification for providing any exclusions. It simply is not good public policy to protect some employees and not others.

RAM recognizes and appreciates the concerns of its members in the states bordering areas and also the other restauranteurs in the states bordering areas, and we would ultimately prefer that this regulatory proposal be enacted on a nationwide basis, but until

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this happens we think this is the best way of protecting our employees, our customers and our employers.

Our position does not have the support of all our members nor of all the restaurants in the state. Our association of over 2200 members represents a broad range of different food service operators in the state, so it is rare when you have unanimous support on any policy initiative. RAM recognizes the rights of reasonable minds to disagree. Admittedly, this proposal represents a big change in the way that we will conduct our business. Change can be frightening and this change to some is particularly frightening. There comes a time, however, when an association has to assume a leadership role and do what it believes is in the best interest of an industry.

Mr. Commissioner, RAM believes that in the interest of public health and equal business opportunity that this is the best way of treating this issue, and it offers Maryland restaurants, its customers and its employees the best approach.

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COMMISSIONER KOELLEIN: Thank you, sir.

(Tape 2)

MS. CAROLYN WEST: Let me just enter Mr. Flanagan's testimony as Exhibit number 128.

(The document referred to as Exhibit 128 was marked for identification and received into evidence.)

MS. CAROLYN WEST: I call Lenny Kaplan.

MR. LENNY KAPLAN: Good morning.

COMMISSIONER KOELLEIN: Good morning, sir.

MR. LENNY KAPLAN: My name is Lenny Kaplan and I'm the owner/operator of the Polo Grill Restaurant in Baltimore City. And approximately a year ago I decided to install a non-smoking policy in the dining room portion of our restaurant, allowing for smoking to still be performed at the bar, in our lounge area. Initially there was some negative impact upon that decision, and it caused me some concern, but we stayed with the policy and we have seen our business significantly rebound and in fact we are busier now

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than we were at the same time last year. I don't attribute that necessarily to smoking or non-smoking, but we overcame the non-smoking stigma that we had initially instituted.

I did what I did because our clientele indicated that non-smoking was their preference. It just felt like a good business decision to eliminate the conflict between smokers and non-smokers in my dining room, and I can assure you there were many, and in some instances almost violent. So rather than have that conflict I chose to potentially cause myself some economic loss and I ran the risk of running a non-smoking restaurant.

It has, in fact -- and I don't want to reiterate what I've already identified, but it has in fact proved to be very positive for those people who care about dining. Unfortunately we have an alternative, or fortunately we have an alternative and they can smoke in the bar, which is why it's so very important that if we pass the smoking law it applied to every conceivable workplace environment including bars,

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taverns, private clubs, et cetera. It has helped manage the restaurant, it's assisted us in seating our guests and inevitably there's a smile on guests' face when they ask for a non-smoking section and we tell them that our entire restaurant is non-smoking, it's received with almost entire pleasure. And I'll be glad to answer any questions you have.

COMMISSIONER KOELLEIN: Thank you, sir.

MR. LENNY KAPLAN: You're welcome.

MS. CAROLYN WEST: I would call on Dr. Frank Kosmakos.

DR. FRANK KOSMAKOS: Good morning, Commissioner, and Counselor. My name is Frank Kosmakos. While I am a businessman who owns and operates two restaurants in Carroll County I also have a Ph.D. in biochemistry. In a prior life I spent most of 15 years as a secluded biochemist. This experience has provided me with a unique perspective to view and analyze the data about environmental tobacco smoke and to weigh those conclusions and concerns against my concerns as an individual person.

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In my opinion the scientific data that I have read in the last few years and have heard today have forced me to view the business world in a different light.

Fact number one: Environmental tobacco smoke is a class A carcinogen. By definition a class A carcinogen is a substance known to cause cancer for which there is no safe level of exposure.

Fact number two: Restaurant workers suffer more medical problems from ETS than any other group of workers in the world. As an example, ETS exposure in restaurants is three to five times higher than in typical workplaces, or eight to 20 times higher than in a domestic environment, equivalent to one and a half to two packs a day just by working in a restaurant. Immunogenicity of restaurant air is 10 to 100 times higher than urban outdoor air, and in workplace comparisons on the air space of restaurants the immunogenicity of restaurants is four to eight times higher than polyurethane manufacturing plants or foundries. The fact that the air space in food

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service establishments is bad is reinforced by the health studies; in California as an example they have shown a one and a half to two times greater rate of lung cancer death in restaurant workers than in other industries, and similar studies have been shown for heart disease as was described earlier in the presentation.

Now in these studies in California when compounding variables are removed to just whether the person is an active smoker, their socioeconomic status, the stress or the social support is factored in, the variable of ETS is assumed to be a prime factor for these high mortality rates.

These facts placed me in a very difficult position. First, morally how can I allow my employees to work in an environment that I know is hazardous to their health? While I am only one business person, collectively as food service operators we employ 138,000 people in Maryland. Second, as a business person what risk of potential lawsuits by my employees do I place in my business; already litigation has been

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successful where employees have received financial remuneration for illnesses attributed to exposure to ETS.

Individually, excuse me, each restauranteur may act alone in his or her decision on how to handle ETS; however, and specifically in these lean economic times, it is very difficult to do what one may consider right for one's customers and for employees and at the same time balance this with the long term economic health of one's business. While personally I deplore governmental interference into business this issue does involve a class A carcinogen and it is inevitable that at some time at some level of government restrictions in smoking will be made.

The proposal before us addresses my business in medical concerns, treats all businesses as equals and places the burden on government. Thank you.

COMMISSIONER KOELLEIN: Thank you, sir.

MS. ELAINE PATRICK: You have two Carroll County restaurants?

DR. FRANK KOSMAKOS: Yes, ma'am.

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MS. ELAINE PATRICK: Now, are you presently smoke free in your facilities?

DR. FRANK KOSMAKOS: No, ma'am.

MS. ELAINE PATRICK: You're not? Okay, thank you.

COMMISSIONER KOELLEIN: Thank you.

MS. CAROLYN WEST: Call Richard McClure.

MR. RICHARD MCCLURE: Thank you for allowing me to testify, I'm Richard McClure, I'm general manager of Carroll's Creek Restaurant in Annapolis, Maryland, and second vice president of the Restaurant Association of Maryland, and a life long resident of the State of Maryland and Anne Arundel County. I'm here to speak on behalf of the regulation. My dining room now in my restaurants are non-smoking, my lounge area allows a choice of smoking.

The variations in laws that we have right now, and I live in the middle of a variation; Anne Arundel County about a year ago passed a regulation that required a non-smoking area, the City of Annapolis which centers in Anne Arundel County never passed the

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enabling legislation in its jurisdiction so those laws don't apply. The only things that apply to us are the voluntary programs that the Restaurant Association had implemented several years before. But I watch and see these regulations coming, read the articles about them, the article that everyone says it works if you do exempt bars and taverns. Arlington Texas did such a thing and they have seen major economic impacts because they have certain segments allowing, certain segments not allowing, they grandfathered in certain restaurants and exempted others.

The other question that I have asked everyone all along through every testimony in the last number of years, what is a bar? Everyone seems to want to exempt bars and taverns, I understand taverns because we have tavern licenses here in the State of Maryland. There is no such thing that I know of in Anne Arundel County as bar license. We have tavern licenses and we have restaurant licenses. So if bars don't exist by law how are we going to define a bar if you want to exempt them, except that it be self-proclaimed? We look for a

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level playing field so that we can all work without the economic impact because I see that as the only way that we won't have the major economic impacts for the businesses. The other ones get to be, as Frank Kosmakos mentioned, that as a carcinogen we are going to see cases in both Workman's Compensation and from groups like ADA for people with asthmatics in the restaurant, and if the state wants to exempt us are they willing to indemnify us and make us not liable? And I doubt that that will ever happen on those parts, that they'd want to pick up Workman's Comp on that side or any other liability.

And that's all I have to say today.

COMMISSIONER KOELLEIN: Thank you, sir.

MS. ELAINE PATRICK: Mr. McClure, your dining area is smoke free?

MR. RICHARD MCCLURE: Non-smoking, because it's adjacent to and without walls and without separate ventilation I can't say smoke free.

MS. ELAINE PATRICK: Okay. How long have you had a non-smoking dining room?

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MR. RICHARD MCCLURE: We, we moved the dining room on April 1 to totally non-smoking; it had gotten to the point that on a Saturday night that I'd have 50 tables and I had trouble keeping 5 tables open for smoking.

MS. ELAINE PATRICK: So it's only been a month?

MR. RICHARD MCCLURE: It's only been a month. Do I have, have I had people complain? Yes, I have. We have set up tables in the lounge, I've got a couple regular lunch customers who will now only eat in our lounge area, but by and large it's been, in a month's time I think there have been three parties that said if they couldn't have a smoking table they wouldn't eat there, the rest have said "Oh, good."

MS. ELAINE PATRICK: So your overall business receipts have remained about the same?

MR. RICHARD MCCLURE: They're ahead of last year.

MS. ELAINE PATRICK: They're ahead of last year.

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MR. RICHARD MCCLURE: So it hasn't had any major -- I think it's weather, prettiest weather --

MS. ELAINE PATRICK: Everybody is talking about that.

MR. RICHARD MCCLURE: In Annapolis we're enough of a resort town that weather is a major factor of when our season starts.

MS. ELAINE PATRICK: Uh-huh. And you're referring to Arlington, Texas?

MR. RICHARD MCCLURE: Yes, an article in Restauraunt Business which is one of our trade journals about their laws that were just enacted, and how it's had major effects in this, in the local county and towns between Dallas and Fort Worth, and it had, it exempted some, and some had been in the permit process so they allowed them to keep what they had had during the permit process. They also have some minor jurisdictions within Arlington that didn't pass enabling legislation so they have differences so that you have about four different classes of restaurants; whether they have smoking, non-smoking, whether they

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have certain percentages. And so the ones that have been required to go fully non-smoking when they're next door to someone who is allowed to keep smoking have had detrimental effects to it.

MS. ELAINE PATRICK: And how long has this been in effect?

MR. RICHARD MCCLURE: I don't know the length, it was, the article is -- I would say that it had to be at least six months to get a lead article in the, one of the journals because they don't respond that quickly to it.

MS. ELAINE PATRICK: Do you happen to have a copy of the article?

MR. RICHARD MCCLURE: No, but I can get you a copy.

MS. ELAINE PATRICK: Okay, Ms. West can give you the address.

MR. RICHARD MCCLURE: Okay.

MS. ELAINE PATRICK: If you'd send it, send it to the --

MR. RICHARD MCCLURE: Certainly.

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MS. ELAINE PATRICK: Thank you very much.

COMMISSIONER KOELLEIN: Thank you.

MS. CAROLYN WEST: Is Roger A. Jenkins --

(Brief off the record discussion.)

MR. ROGER A. JENKINS: Good morning, Mr. Commissioner.

COMMISSIONER KOELLEIN: Morning.

MR. ROGER A. JENKINS: My name is Roger Jenkins. I hold a Ph.D. from the University of Wisconsin-Madison in analytical Chemistry. I am employed at Oak Ridge National Laboratory which is a large multiprogram applied basic and applied research facility in East Tennessee. It's owned by the U.S. Department of Energy. My current position is group leader for environmental monitoring in the chemical and analytical sciences division of ORNL. In the more than 18 years since I earned my doctorate I have been principal investigator for numerous projects for the US Departments of Energy and Defense, National Institutes of Health and private and educational concerns. My professional interests include the chemical

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characterization of airborne mixtures including process effluents, fugitive emissions, military obscurants and tobacco smoke. I have worked in the general area of characterization of tobacco smoke and methodology for the definition of animal inhalation exposures to smoke aerosols since 1976. These studies have been supported by the Center for Indoor Air Research, the Council for Tobacco Research, the University of California at Davis, the National Institute on Drug Abuse and the National Cancer Institute. I am co-author of a book entitled The Chemistry of Environmental Tobacco Smoke: Composition and Measurement, and have published through both symposium proceedings and peer-reviewed literature concerning ETS levels in public places.

I am present today not as an advocate for or against any pending legislation or rulemaking, but rather as a scientist who is conducting a study and generating information which you might find useful in your deliberations.

On March 16th of this year I privately briefed representatives of the federal Occupational

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Safety and Health Administration and the Environmental Protection Agency on this study. Our sponsor, the Center for Indoor Air Research of Linthicum, Maryland, believed that knowledge of this study and the kind of data that it should produce would be of interest to those involved in these deliberations.

Along with Dr. Michael R. Guerin of Oak Ridge National Lab, I am co-principal investigator for what is to my knowledge the largest study ever conducted in the United States of the personal exposure of individuals to environmental tobacco smoke in the home and workplace. When the study is completed approximately 100 subjects in each of 16 cities around the United States, or a total of 1600 individuals, will have participated. The individuals are contacted either through random telephone dialing or through the use of a marketing research firm database. They are screened to ensure their qualification for the study, they're informed of the fact that this is an indoor air quality study although not told specifically that it's related to environmental tobacco smoke. To be included

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in the study all the participants must report themselves to be non-smokers, at least 18 years of age and work outside the home at least 35 hours a week. I've provided some more detail concerning the study design, but I'll just skip that, it's in my written comments.

The, we are measuring exposure to environmental tobacco smoke using a number of components in the indoor air including respirable suspended particulate matter, UV absorbing particulate matter, fluorescing particulate matter, solanesol which is a tobacco specific terpene, nicotine, 3-ethenyal pyridine, and myosmine.

In addition to the environmental tobacco smoke markers which are collected by the sampling pumps that these individuals wear, each subject provides a saliva sample at the beginning and at the end of their participation interval so the smoking status and potential exposure to ETS can be assessed. That is accomplished by determining the amount of cotinine in saliva; cotinine, as you know, is a metabolite of

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nicotine.

The subjects are also, provide a considerable amount of demographic information, so we have all kinds of information regarding their lifestyle and their perceived exposure to activities which may affect the quality of the air that they breathe including cooking, smoking, construction, maintenance activities, et cetera.

Ultimately the data that we are gathering consists of an eight hour determination of their second hand smoke exposure in the workplace and approximately 16 hour determination of their ETS exposure at home, while shopping, commuting, or engaged in other non-work related activities.

Our study is still in progress. We believe that the results should be subjected to peer review prior to any general release to the public; however, I would be happy to provide some of the preliminary data from the first few cities in the study to interested individuals upon request, with the understanding that the data is of a preliminary nature. We are likely to

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complete the field data collection phase of this study in June of this year, the final report to the sponsor will be issued within six months after that.

When our study is completed it should provide a considerable amount of information regarding both home and workplace exposures to environmental tobacco smoke. Some of the important issues which should be able to be addressed from the results of our study include the following: The relative magnitude of home and workplace exposures -- I might note that several of the speakers today have indicated the need to make assumptions concerning the relevant magnitude of home or workplace exposures, our study will provide hard data on that. It'll provide differences -- well, will provide data concerning occupational differences in workplace exposures because we have occupational data on all the individuals that are participating in this study. It'll also provide information regarding exposure levels in more modern environments where smoking has been restricted to selective locations; many of the studies that have previously been reported

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are five to 10 years old and we don't have moderate information. It'll also afford the opportunity to address comparisons of exposures in non-smoking and in smoking homes and workplaces and provide information regarding misclassification of subjects regarding their smoking status. This may be of interest determining with relatives to the ETA risk assessment. And also provide data as to the utility of salivary cotinine as a potential indicator of ETS exposure and the role of diet on salivary cotinine.

As an aside I have recently reviewed a report of a somewhat similar study conducted for the Center for Indoor Air Research by the Hazleton Laboratories in the United Kingdom. The study involved only about a quarter of the number of participants as the Oak Ridge National Laboratory study and involved the acquisition of 24 hour exposure samples. Interestingly, in the Hazleton study, for those individuals who reported ETS exposure in only one venue or location, either home, work, leisure or travel, workplace exposures to nicotine were about half those that occur in the home.

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This is in contrast to one of the interpretations anyway at least of the 1992 EPA report on passive smoking which indicated that workplace concentrations of ets were, quote, "Analogous" unquote, to residential concentrations. Whether or not such is true in the United States will have to await a detailed examination of the study which I have described to you today; however, I might indicate as an aside that if the trends of our preliminary data hold the exposures away from work, including the home, are probably several factors greater than those present in the workplace, and this is general, generally overall and not specific to any particular occupation.

I thank you for the opportunity to tell you about the study which we are conducting. I'll be happy to answer any general questions at this time if you think that would be appropriate.

MS. ELAINE PATRICK: Yes, you say you have preliminary data from the first few cities, how many cities do you have --

MR. ROGER A. JENKINS: We've analyzed the

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data for the first six cities up to this point in this study. These are cities scattered all over the United States.

MS. ELAINE PATRICK: And your preliminary trends in exposures away from work are several trends higher, is that what you said?

MR. ROGER A. JENKINS: Away from work, basically in the home or commuting, what have you, are several times -- it's a little difficult to say exactly how many now and depending on what smoke marker that you use, but we're looking, generally our numbers are running three to four times greater for those, the levels of markers are three to four times greater than what they would be in the home, and of course -- or in the workplace, rather. And if you spend twice as much time, say away from work as you do at work, then the exposures would be a factor of two greater than --

MS. ELAINE PATRICK: Now you're breaking down all of these, so you have, did you say two different monitors?

MR. ROGER A. JENKINS: Yes, that's correct.

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We have, we basically, they're -- The individuals wear a pump, sampling pump and collection apparatus while they're at work and then they put on an additional sampler or a different sampling apparatus and pump when they leave work and go home, and they put that by their bedside while they're sleeping at night and they turn it off in the morning when they get up.

MS. ELAINE PATRICK: So they have a work pump and another one --

MR. ROGER A. JENKINS: Basically that's correct. Yes.

MS. ELAINE PATRICK: And let's go through some of these markers. You say it depends on which marker?

MR. ROGER A. JENKINS: That, that's correct, Counselor.

MS. ELAINE PATRICK: Do, do you have it at your fingertips or is this unfair?

MR. ROGER A. JENKINS: I have some of it at the fingertips. Our, my upper level management was somewhat reluctant for me just to generally produce all

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this information at a public hearing because it hasn't been subjected to peer review, but I would say that just on the tip of my tongue here that the markers, some of the gas phase markers like 3-ethenyl pyridine and nicotine are about a factor of three to four. And again, this is just preliminary data from the first six cities you understand. The fact that they're three to four greater away from work than they are at work. And for some of the, one of the tobacco specific markers, solanesol, which is in particulate matter, it's very difficult to determine that because the levels of solanesol in the workplace are so very very low, but even if we use our detection limits it's kind of a lower limit, it looks like a factor of 8 difference.

MS. ELAINE PATRICK: Now how do you control for what policies, smoking policies in the different workplaces?

MR. ROGER A. JENKINS: These, basically these, the individuals that are in the study are segregated, okay? In other words we have individuals that are, that are in workplaces where there are no

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restrictions and workplaces where there are restrictions, and the data that I'm reporting to you, you know, I'm telling you about right now is that data which is where the workers are working in an area where there are essentially no restrictions as to smoking.

MS. ELAINE PATRICK: And are you getting any kind of diary information or any information about their particular exposures --

MR. ROGER A. JENKINS: Yes.

MS. ELAINE PATRICK: -- at times when --

MR. ROGER A. JENKINS: Yes, the subjects fill out an hour by hour diary as to the amount of smoking that they observe around them, the amount of, everything from, you know, how many times they see somebody open up one of the, the corrective fluids, you know, that would, you know, produce, you know, an airborne exposure of materials, the burning candles, to incense, or whatever. So they, basically they fill out this diary on an hour by hour basis throughout the course of the day and also for their home exposures as well.

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MS. ELAINE PATRICK: And then when you're getting the figure of approximately three to four times greater for workplaces, assuming there are no restrictions at work, do you also control these particular people's exposures that they're reporting in the diaries?

MR. ROGER A. JENKINS: Yes. That's correct. One of the things, one of the things that these individuals do is sort of self report or through a series of screening questions whether or not they are, really work in a smoking or non-smoking workplace, okay? And one of the things that we found interesting that in many cases they claim to work in a workplace where smoking is in fact restricted in some way, but in fact they never report any observations of any cigarettes being smoked around them, so in those particular cases we, we consider them working in a non-smoking workplace if they don't actually observe cigarettes being smoked around them.

MS. ELAINE PATRICK: So they would actually then go -- So someone who reports -- So first you

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segregate them by the kind of policy they report, but then when you look at their diaries if you see that someone is not reporting any observations of smoking then even if they're in a place that has no restrictions you move them to --

MR. ROGER A. JENKINS: Well, no, no, not necessarily. Actually we have, we have categories. There's a number of -- Again, this is, the data is being examined for many different aspects, and, because this is one of the problems, of course, of reporting on a study that's in progress --

MS. ELAINE PATRICK: Is all the data in?

MR. ROGER A. JENKINS: No. Not all the data is in.

MS. ELAINE PATRICK: You said June --

MR. ROGER A. JENKINS: The June of '94, we're actually, we've completed field operations in 13 of the 16 cities in this study, it's because of -- As you can guess from the magnitude of this study it takes a long time to get this, all of the data in. We've --

MS. ELAINE PATRICK: When did you start?

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

MR. ROGER A. JENKINS: We started in May of 1993. Just the logistics of handling all these, you can't imagine how --

MS. ELAINE PATRICK: Oh, you'd be surprised.

MR. ROGER A. JENKINS: Yeah, I'll bet you can. Okay. Anyway, we have several categories and we've looked at this data from a number of different angles as to whether or not individuals are actually in a workplace where smoking is restricted versus workplaces where they say, the individuals report that there are restrictions but they actually observe cigarette smoking, or places where individuals report no restrictions but they actually observe smoking and all sort of thing. For this factor of three to four, this, for those individuals which, to basically be included in this, in this particular data assessment they had to have reported smoking both in their diaries and also from a final last visit survey that they have, so they have to have confirmed smoking around them for us to make this assessment.

MS. ELAINE PATRICK: And when you say a

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factor of three or four, you know, I'm not so good with these micrograms per cubic meter and all that stuff but I'm going to give it a shot here. Please don't boo, hold your applause too. Say, let's just take a hypothetical to make it easier for me. Let's say that there's one microgram of nicotine measured per cubic meter in a residential setting, or in the work setting. You're telling me that you're getting, say, three to four --

MR. ROGER A. JENKINS: Actually the numbers --

MS. ELAINE PATRICK: Tell me the numbers you're getting.

MR. ROGER A. JENKINS: Well, you really are pinning me down, Counselor. However, if you'll permit me to look at some of my notes that I made. For example, the nicotine levels -- of course there are some, lot of scientists, myself included, have raised issues about just, using just nicotine as a marker of environmental tobacco smoke, but for example in the, in smoking homes the level of, the median level of

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nicotine -- you understand the different between median and -- The median level --

MS. ELAINE PATRICK: Just micrograms, not the medians.

MR. ROGER A. JENKINS: Okay. Median level of nicotine was .78 micrograms per cubic meter in homes where smoking was confirmed to be present. And in non-smoking homes, okay, the level of nicotine was .032. Of course one question one might add is how does one have nicotine present in non-smoking homes, and it could be anywhere from off gassing of individuals garments when they come in from, you know, have been exposed to smokers some other place or what have you, but the levels are very very low in non-smoking homes. To make the comparison in the workplace --

MS. ELAINE PATRICK: In some of these no restriction workplaces.

MR. ROGER A. JENKINS: Okay. Okay, for the -- this is a slightly different categorization, and again this is one of the problems in dealing with preliminary data, but different characterization of

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smoking homes which smoking was confirmed the median level of nicotine was 08 --

MS. ELAINE PATRICK: These are smoking homes we're in now, or --

MR. ROGER A. JENKINS: I'll get to smoking workplaces. Okay, smoking workplaces --

MS. ELAINE PATRICK: No, that's okay, finish the smoking homes, I'm not --

MR. ROGER A. JENKINS: Smoking homes were 08 micrograms per cubic meter, and smoking workplaces was .19 micrograms per cubic meter, about a factor of four.

MS. ELAINE PATRICK: Now you say this is a different group of homes than those other --

MR. ROGER A. JENKINS: Well the criteria for inclusion, again because it's preliminary data, I note there's some differences in the number of participants, so we may -- some of this data, again, was put together very hastily for another, another presentation I provided last month, OSHA, and I haven't had a chance to rereview it yet, but I just brought what I had done then with me. But for example, the fluorescing

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particulate matter which is an indicator of combustion related particulate matter in the home, in the home was about 5 micrograms per cubic meter whereas in the smoking -- this is in smoking homes. In smoking workplaces it was about 1.6 micrograms per cubic meter, so the difference was about three. Factor of three difference.

MS. ELAINE PATRICK: What kind of -- now these are wearing personal monitors and --

MR. ROGER A. JENKINS: These are active, these are active sampling. These individuals wear a sampling pump that sucks the air through a sample collection device which we examine both, collect both particulates and vapor phase components.

MS. ELAINE PATRICK: And it's the same device for both phases, or --

MR. ROGER A. JENKINS: Yes.

MS. ELAINE PATRICK: -- non-smokers have the same device, the same type of --

MR. ROGER A. JENKINS: The pump for the home is essentially the same as the pump for work, except

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that the pump for home has a bigger battery system in it so it can go for the longer period.

MS. ELAINE PATRICK: Last for 16 hours. How often do you have to replace a battery for that?

MR. ROGER A. JENKINS: We recharge the batteries every night, or every time we get them back, yeah.

MS. ELAINE PATRICK: And how often do you get them back?

MR. ROGER A. JENKINS: Well these, basically these are 24 hours sampling, basically we provide 24 hour segment of the individual's life, and for example if the individual would pick up the sample, the sampling system on a Monday night he would, he or she would measure the work exposure on Tuesday morning then their home exposure on Tuesday evening and Wednesday, early Wednesday morning while they're sleeping, turn it off and return it to us on Wednesday evening.

MS. ELAINE PATRICK: Uh-huh. And does one, do you take multiple samples from the same subject, or one sample per subject or --

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MR. ROGER A. JENKINS: No, each subject provides two sets of samples. The home and workplace samples.

MS. ELAINE PATRICK: But how many times do they --

MR. ROGER A. JENKINS: Just once. One, basically one work period and one at home or away from work period.

MS. ELAINE PATRICK: So then basically for each -- you say you have 1600 samples, 1600 work samples and 1600 home samples?

MR. ROGER A. JENKINS: Ultimately, yes, that's correct. Yes.

MS. ELAINE PATRICK: Okay.

MR. ROGER A. JENKINS: Believe you me, I wish that this study was completed and I could provide you with a peer review copy of all of the, of the report or whatever, but as I said, this is still in its preliminary stages.

MS. ELAINE PATRICK: Who is your sponsor?

MR. ROGER A. JENKINS: The sponsor is the

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Center for Indoor Air Research of Linthicum, Maryland.

MS. ELAINE PATRICK: Who is that?

MR. ROGER A. JENKINS: Well, they're sort of a consortium of a number of, if industries interested in indoor air quality, everything from tobacco companies to chemical industries, Carrier Air Conditioning is a sponsor for the Center.

MS. ELAINE PATRICK: And so they just --

MR. ROGER A. JENKINS: Basically they contract this work to us, and --

MS. ELAINE PATRICK: Contract it, and you had --

MR. ROGER A. JENKINS: Pardon?

MS. ELAINE PATRICK: You had to write a grant for this?

MR. ROGER A. JENKINS: We write a proposal and the proposal is what amounts to a contract between Martin Marietta Energy Systems, which is our particular contractor at Oak Ridge National Laboratory. Without having to explain to you all of the different -- Within the Department of Energy --

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MS. ELAINE PATRICK: Sounds like the Department of Energy.

MR. ROGER A. JENKINS: Right, that's correct, but I'm not a government employee because none of the national laboratories are -- The scientific staff of the national laboratories are not government employees, they're contractor employees. If you work at Los Alamos Labs you're legally an employee of the University of California, you know? If you work at Argon National Laboratory you're legally an employee of the University of Illinois.

MS. ELAINE PATRICK: So you're really --

MR. ROGER A. JENKINS: Martin Marietta Energy Systems. That's correct.

MS. ELAINE PATRICK: And you work at the lab.

MR. ROGER A. JENKINS: Right.

MS. ELAINE PATRICK: Have you, have you calculated what the margin of error in your sampling, in your numbers you have been giving me might be, or not --

MR. ROGER A. JENKINS: It's really, it's

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really too early to say. I mean, obviously the data is very very scattered, and I haven't had time to do things like produce geometric means and stuff like that which would give us a little bit tighter feel for what the variation of the data is. I mean, again, I wish I had all this information for you. Believe you me, I wish I had -- Again, but I'm not advocating here one way or the other. Both sides on the issue could take my data and I'm sure run with parts of it.

MS. ELAINE PATRICK: Who asked you to come today?

MR. ROGER A. JENKINS: Our sponsor, the sponsor. I mean, they're down in Linthicum which isn't too far from here, and --

MS. ELAINE PATRICK: Oh, okay.

MR. ROGER A. JENKINS: -- they felt like you folks ought to be aware of the fact that this study is going on, because I -- well, the Executive Director didn't say specifically why, but I would imagine that a lot of the assessments that have been done up to now have been with data that's of older data, you know,

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data that was taken several years ago. I mean, some of the data we're getting now is different from data that we published five and six years ago, just because smoking habits have changed, you know? And this represents a relatively new study and relatively sophisticated technology. I mean, that's the other thing, is the technology wasn't available 10 years ago to --

MS. ELAINE PATRICK: Which technology was that that wasn't available --

MR. ROGER A. JENKINS: Well, basically the methods for determining nicotine and other indicators of tobacco smoke exposure really weren't available 10 years ago. I mean, just the analyzation methods hadn't been developed.

I've taken a lot more than my 10 minutes, but it's --

MS. ELAINE PATRICK: No, you haven't, I've taken a lot more.

MR. ROGER A. JENKINS: That's okay.

MS. ELAINE PATRICK: They don't set the timer

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on me.

COMMISSIONER KOELLEIN: Thank you, sir.

MR. ROGER A. JENKINS: I guess that's it.

MS. ELAINE PATRICK: I think I have more questions but they must not be too significant because I forgot them.

MR. ROGER A. JENKINS: Okay. I do that all the time.

MS. CAROLYN WEST: Commissioner, I would just enter in Mr. Jenkins' testimony as Exhibit number 129.

(The document referred to as Exhibit 129 was marked for identification and received into evidence.)

MS. CAROLYN WEST: I don't know whether or not you may want to break for lunch now, and --

MS. ELAINE PATRICK: Let's keep on going.

MS. CAROLYN WEST: -- take --

COMMISSIONER KOELLEIN: One more.

MS. CAROLYN WEST: We, I would go down the list. We have attempted to call these individuals

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yesterday and inform them that they would not be testifying until late, later this afternoon, so --

MS. ELAINE PATRICK: Well, can we do it the other way. Is there --

MS. CAROLYN WEST: I can look at the sign up sheet.

MS. ELAINE PATRICK: Yeah, look at the sign up sheet, see who is here. Go off the record.

(Off the record.)

(Back on the record.)

MS. CAROLYN WEST: -- Hannan, from Maryland GASP?

MR. JAMES HANNAN: Thank you, thank you, Commissioner. My name is James Hannan, I'm from Maryland GASP, we have about 1,000 members throughout the state of Maryland against inclusion.

Very short testimony, I just wanted to emphasize the argument about losing business by prohibiting smoking, and Mr. Fogle already addressed that 70 percent of people are non-smokers. If the smokers are not going to come from other states non-

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smokers will come in and business will have to be better than the otherwise. Thank you.

COMMISSIONER KOELLEIN: Thank you, sir.

(Brief off the record discussion.)

MS. CAROLYN WEST: I'd call Domingo Aviado. Let's go off the record for a minute.

(Off the record.)

(Back on the record.)

COMMISSIONER KOELLEIN: Let's go back on the record, please.

DR. DOMINGO AVIADO: Good morning, or good afternoon, Mr. Commissioner and Madam Counsel. I was born in the Philippines and my, and migrated to the United States after the Japanese war in 1945 to complete my medical education at the University of Pennsylvania. I obtained my medical degree in 1948 and started research and teaching in medical pharmacology progressing from instructor to professor of pharmacology from 1948 to 1977.

Thank you, thank you. My first research project at the University was on the subject of

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planned/derived alkaloids specifically nicotine and verapidime. At the University of Pennsylvania Medical School my sponsored research was funded by the Department of Defense for the Administration, Consumer Product Safety Commission, National Institute of Health, the Council for Tobacco Research and several pharmaceutical companies.

During the past 45 years 90 percent of my research funding was derive from United States Governmental Agencies and 10 percent from private industries in Asia, including the Philippines, Europe and the United States. Since 1978 I've been President of a consulting firm called Atmospheric Health Sciences in Short Hills, New Jersey, which provides consulting services in the fields of pharmacological sciences listed in the slide,. occupational toxicology, and medicine. Approximately half of my research activities during the past 45 years relates to the subject of my testimony; I have published over 300 articles, 10 monographs, one textbook of pharmacology and two dictionaries.

The MOSH Board proceedings of the December

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1993 hearing and the Board's report were made available to me by representatives from Philip Morris who requested that I present my views at this hearing. I welcomed this opportunity, Mr. Commissioner, because I feel that my extensive research in this area may be helpful to the Commissioner in his deliberations.

My research activities and review of the literature on industrial chemicals are covered in two chapters in the 1993/1994 edition of Patty's Industrial Hygiene and Toxicology. This note at the title of the first one, chapter, is called fluorine containing organic compounds and I would like to read the opening sentence which reads as follows:

"During the third millennium A.D., medical practice will most likely be eclipsed by events relating to fluorine containing organic compounds reviewed in this chapter. This sweeping prediction is based on two developments prior to the end of the century of the millennium; I'm talking about the depletion of the ozone layer," and if someone will invite me during the next millennium to testify I will

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defend the contents of this chapter. Today, however, my topic relates to the complex mixtures of tobacco smoke and the occupational environment, and I have copies of this chapter from the book that was just published, and the opening sentence there is very very relevant to this hearing. My research activities and review of the literature as I said on industrial chemicals are covered in this chapter. I might mention that these two chapters were extensively reviewed by the editors and several outside reviewers. For the past four decades Patty's has been widely regarded as the most authoritative references on the subject of industrial hygiene and toxicology.

My chapter in Patty's and several of my other publications previously were provided to the MOSH Board, Maryland Board, but they were not discussed in the Board's report. My CV and list of my publications and a reprint of my chapter is attached to this written version of my testimony.

The key document by MOSH Board is 1992 Environmental Protection Agency review entitled

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Respiratory Health Effects of Passive Smoking. In 1978 when I was much younger I was appointed as a member of the Scientific Advisory Board and was the physician member of the Clean Air Scientific Advisory Committee mandated by the 1977 Clean Air Act. Although I'm not always in full agreement with the opinions of my successors at the EPA as a Scientific Advisory Board, I respect those opinions and my testimony reflects this fundamental attitude. In 1990 I presented comments on the toxicological shortcomings of a draft of the EPA 1990 review. Those comments previously were submitted to the MOSH Board. I also disagree with any attempt to apply the EPA's conclusion to workplace exposure.

In my Patty's chapter I reviewed diseases in relation to ETS and purported ETS constituents. I concluded that the levels of purported ETS constituents are unlikely even to approach workplace standards, and I must interject that after hearing the previous testimony of Dr. Jenkins my prediction that I wrote is, has turned out to bet true. OSHA has adopted permissible exposure limits, PEL's, for workplace

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exposure to various chemical substances including some for the substances also found in the ETA. These PEL's specified allowable concentration of substances for eight hours a day, 40 hours per week for a working lifetime at which no adverse health effect would be anticipated. The American Conference of National Hygienists have recommended exposure levels which they call threshold limit values for these same substances which in some instances are significantly lower than OSHA's PEL's. For example, levels of carbon monoxide reported in ETS in comparison with it's ELV do not support claim that ETS require regulation in the occupational environment. In the regulatory context carbon monoxide has always been considered as a marker for levels of other constituents in complex mixtures reported from combustion. It has often been presented, assumed, that if carbon monoxide is below it's ELV then other constituents of the complex mixture would also be expected to be below their respective ELV's. There are only minute levels of carbon monoxide in ETS, as much as 3,100 times less than in mainstream smoke, and

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requiring as many as 50 cigarettes burning continuously, simultaneously, completely, to exceed in a ventilated 100 cubic meter chamber to result in the ELV for carbon monoxide. These minute levels of carbon monoxide in ETS caused to serious question any claim that ETS exposure can cause cardiopulmonary disease in non-smokers.

There are 29 reported sidestream smoke constituents where ELV's have been established, but only 11 of these substances actually have been detected in ETS. For most of these 29 substances it would require hundreds for instance of carbon dioxide, or thousands, 222,000 methopyrine, or one million cigarettes burning, I repeat, simultaneously and completely to exceed ELV of pyridine.

I'm going through this arithmetic just to show the futility of exceeding the ELV by burning half a million cigarettes. In my Patty's chapter I have identified 32 industrial chemicals for which occupational heart disease, occupational exposure has been associated with heart disease. Of these 32

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industrial chemicals 21 are purported ETS constituents based on their detection in sidestream smoke. But only eight out of these 21 are substances heretofore that have been detected in environmental tobacco smoke. However, at levels below their respective ELV's none of these 21 substances have been reported to be associated with heart disease or other adverse physiological effects. Therefore, it is my opinion in harmony with the previous speakers that the available studies do not, I repeat do not support a judgement that ETS exposure is associated with any form of occupation related heart disease.

Let us examine occupational neoplastic diseases. Proponents of an association between ETS and neoplastic disease rely, I repeat rely on the estimate that there are at least 34 constituents in sidestream smoke with reported carcinogenic activity in experimental animals. About a dozen of these substances have been reported in ETS but at concentrations so low that a non-smoking worker must be exposed to the concentrated emissions of hundreds of

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thousands or even millions of cigarettes to exceed threshold barriers. Only one of the substances found in sidestream smoke, nickel, is classified as a lung or pulmonary carcinogen. And the levels of nickel in sidestream smoke are extremely, extremely small. It would take several million cigarette, cigarettes ignited simultaneously in a 100 cubic meter room. That's just about the size of a bedroom in the Hilton down the, down Route 695, the size of a bedroom there at the Hilton Hotel, of nickel compatible to the levels used in animal studies for nickel carcinogenesis. Nickel has been detected in environmental tobacco smoke, therefore it is my opinion that in an occupational setting ETS does not, again I repeat does not meet OSHA's criteria for designation as a potential occupational carcinogen, nor is ETS present at the level sufficient to constitute a significant risk.

Finally, Mr. Commissioner and Madam, insufficient scientific basis is my last subject. There is insufficient scientific basis for claims that ETS exposure in the occupational environment is

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associated with cardiopulmonary disease. In making recommendations to OSHA both the American Conference of Government Industrial Hygienists and the National Institute of Occupational Safety and Health rely on data involving worker exposure in the occupational environment. There are almost no such occupational data on ETS and little available data where it is thoroughly examined in ETS context. Moreover, data on presumed, presumed household ETS exposure as in spousal smoking studies cannot, I repeat, cannot be applied to workers because exposure conditions and potential compounding factors are much different in the occupational environment. These compounding factors that haven't been mentioned by the first speaker this morning related to ETS exposure in workplace are different from factors influencing spouses and children in studies of household exposure. Dietary factors, household pollution may influence the incidence of spousal and childhood diseases. There are also the problem of familial inherited factors that had to be considered before anyone can transfer spousal or

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household diseases to occupational diseases.

On the other hand, workers are exposed to industrial chemicals and outdoor pollutants as well as work related stress. Familiar pressure or inherited are applied to susceptibility to cardiopulmonary disease you have applied occupational group. The most important body of information can only be derived by comparing the occurrence of occupational diseases in two population groups; workers exposed to hazardous substances and a control group of unexposed workers. For ETS exposure there is no reported balance study comparing exposed workers and non-exposed workers in the work environment. Such a study cannot be arrived at by interpolation from household exposure. Such a study would include several medical examination of workers enrolled in a prospective study, selection of controls with similar risk factors, repeated measurement of exposure levels which I understand from Dr. Jenkins is very practical at the present time, and diagnoses of occupational diseases clinically and after death. As far as I know such a study has not been

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

conducted. Data on active smoking in workers or on mainstream smoke or side stream smoke cannot, I repeat, cannot be extrapolated to ETS because ETS differs from those other form of potential tobacco smoke exposure in many important ways including physical and chemical characteristics, levels of air pollution and nature of exposure. Only about 100 of the 3,700 substances reported in mainstream smoke have been reported in sidestream smoke, and of this 100 only about 20 have actually been detected in ETS and in air. After, potential components of ETS from mainstream smoke or sidestream smoke are so diluted that they are either undetectable by currently available analytical methods or have undergone chemical transformation in mixing with clean air.

Although sidestream smoke is sometimes reported to have higher concentrations of several constituents converted from mainstream smoke, this is not toxicologically relevant to ETS because of the immediate and continuous air dilution of sidestream smoke, as they appear in air, ETS constituents are

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typically hundreds to thousands of times more dilute in mainstream smoke. For example, the concentration of nicotine in ETS has been calculated to be up to 144,000 times less than the concentration of nicotine in mainstream smoke.

In conclusion, in conclusion, Mr. Commissioner and Madam, in summary I have presented highlights of my Patty's chapter to assist you, the Commissioner, in considering the Board's conclusions relating to occupational diseases associated with the ETS exposure. There is insufficient biomedical basis to support the general proposition that ETS exposure causes occupational diseases. Thank you.

COMMISSIONER KOELLEIN: Thank you, sir. At this time we'll take a little lunch break, we'll reconvene at 1:00. Please be prompt, we have over 50 people who signed up today, we intend to stay until the end and thank you very much for your cooperation.

(Whereupon, the proceedings were recessed to reconvene at 1:00 this same day, May 3, 1994.)

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AFTERNOON SESSION

(1:00 P.M.)

MS. CAROLYN WEST: I'd like to call Dr. Elizabeth Fontham, please? And, Commissioner, I believe you've been provided with her testimony, and may I mark that into evidence as number 131?

COMMISSIONER KOELLEIN: All right, thank you.

(The document referred to as Exhibit number 131 was marked for identification and received into evidence.)

COMMISSIONER KOELLEIN: Good afternoon.

DR. ELIZABETH FONTHAM: Good afternoon. Is there a slide clicker? Okay.

COMMISSIONER KOELLEIN: Please proceed.

DR. ELIZABETH FONTHAM: Good afternoon. I'm going to try to do this without my magnifying glasses but I may have to put the clicker down any minute. My name is Elizabeth Fontham, I currently hold an appointment as associate professor in the Department of Pathology at the Louisiana State University Medical

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Center in New Orleans, Louisiana. I was invited to come here today by the Attorney General's Office to provide some information about a study of environmental tobacco smoke and lung cancer in which I've been involved. I was the National Coordinator and the principal investigator of the Louisiana Study Center in this multi-center study of environmental tobacco smoke and lung cancer, it was a case controlled study. This study was included in the EPA's recent 1993 report and I understand that the estimate for workplace exposure from our study is being used here in Maryland, and so I thought I would share with you some of the methods and results from our study and answer any questions you might have.

Our study was initiated in 1985 -- Whoops, let me go back -- specifically to evaluate the association of environmental tobacco smoke with risk of lung cancer in lifetime non-smoking women. You can see from the list of names there that there are lots of coinvestigators that who been involved in the project over time. The study was designed to minimize some of

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the methodologic problems that have been of concern in previous studies of ETS and lung cancer; specifically misclassification of smoking status, in other words calling actual smokers non-smokers or believing that they were; the accuracy of the case diagnosis, making sure that lung cancer cases were in fact actually lung cancer cases; addressing the issue of recall bias; looking at environmental tobacco smoke exposures from sources in addition to spouse, we know that that is certainly not the only place that exposures can occur; and to control potential confounders.

The findings of the first three years of our five year study were published in November of 1991, a second report will be issued this summer, but you all are using the 1991 published report and it's that report to which I will refer in this talk. Because of the large number of lifetime non-smokers in our study in that three year report as well as the study design that we use it contributed the greatest weight to the US risk estimates in the EPA report, so I would briefly like to review how the study was conducted and some of

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our findings.

This is a population based case control study of lung cancer in women who never used any type of tobacco, and in this study we used a fairly standard definition of tobacco use; it was defined as 100 or more cigarettes smoked or any other form of tobacco use for more than six months. Geographically our study included five metropolitan areas: Metropolitan Atlanta, Houston, Los Angeles, New Orleans and all of the San Francisco Bay area; and so that's about a population of 18 and a half million people or about 8 percent of the US population. Obviously not a random sample of the US population, it represents those five areas.

We identified our cases, our case selection was by rapid case ascertainment procedures which means that in each of these five geographic areas we went to every hospital in those geographic areas weekly or biweekly and went through the pathology reports for newly diagnosed cases of cancer of the lung. It's particularly important in lung cancer to try to

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identify the cases quickly because lung cancer is, unfortunately, a rapidly fatal disease and you would like to be able to interview as many cases personally as possible; that is, to have a small proportion of next of kin respondents in your case control study.

Upon completion of case ascertainment we ascertained over 17,500 eligible cases or screens in order to come up with the 100, 400 MSN and 600 and some odd in our final study. To be eligible the cases had to be English, Spanish or Chinese speaking, our questionnaire was translated into those three languages, ages 20 to 79, had to have a histopathologically confirmed diagnosis of primary carcinoma of the lung with no previous history of cancer and be a lifetime non-user of tobacco according to procedures that I'll describe in just a minute.

We had two control groups in our study and we selected two control groups in the first three years in order to evaluate response bias; the way people answer question, because that's always a consideration when you're interviewing ill cases and healthy controls.

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When the cases have been diagnosed with a cancer and so they may recall a response slightly differently than other people in the general population. The primary control group, however, is the population control series and they were selected from the general population of these same cities by random digit dialing and for women who were 65 years of age and older we random sampled from the Health Care Financing Administration Files, that's the Medicare files. They were frequency matched to cases on age; less than 50, 50 to 59, 60 to 69 and 70+ years in an approximately 2 to 1 controls to case ratio, and they met the same eligibility criteria; cases for age, residence, language and tobacco use.

The second control group that I mentioned is the one that we picked because they were also ill and they'd also been diagnosed with cancer but their disease is not known to be associated with passive smoking. They were a sample of females diagnosed with primary cancer of the colon during the same time period, during the first three years, who met the same

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eligibility criteria. When you compare your lung cancer cases to each of the control groups, if you get the same or similar estimates of risk you have more assurance that the estimates of risk are in fact real and not inflated or deflated because the cases remembered things in a different way or reported them in a different way.

We used a multi step procedure to determine lifetime non-smoking status; we didn't just look at it once we did a review of the medical record of each potentially eligible lung cancer case, and there were about 17,500 of them, as well as the colon cancer control series. We reviewed the charts for information on tobacco use; if the patient was identified in the medical record as being a current or an ex smoker she was automatically disqualified from the study. We then contacted the personal physician of each of the still potentially eligible cases in colon cancer controls who we believed might be lifetime non-smokers and asked the physician about the patient's smoking history. Any study subjects, either lung cancer cases or controls,

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who were so identified by their physician as being a current or former smoker were also considered ineligible. At that point we got a group of lung cancer cases, colon cancer controls and a random sample of women in the population who at that point we believe are all lifetime non-smokers. They were all then contacted by telephone and asked a series of questions about their tobacco use to make sure that they had never smoked 100 or more cigarettes or used tobacco for greater than six months. If they answered correctly on those questions we repeated the questions again when we went to their house for an interview, giving them ample opportunity to change their minds. Only about 5 percent of our lung cancer cases were lifetime non-smokers; the vast majority of women with lung cancer have smoked at some time in their life.

At the time of the interview we did something else, we requested a sample of urine because we know from other studies that a small proportion of people who identify themselves as non-smokers in fact have levels of tobacco compounds, nicotine and cotinine in

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their bodies that suggests that they are in fact active smokers at the time that they identify themselves as non-smokers. So we requested a urine sample from all of our study subjects who were interviewed. Interviewers were non-smokers to eliminate the unlikely possibility of contaminating the urine sample and we stored the specimens at -20 degrees centigrade until they were shipped to the American Health Foundation for analysis of cotinine and creatinine. This biochemical determination was used to verify current smoking status; obviously there is no biomarker of lifetime smoking status but we can look at current, and if someone had elevated levels they were excluded from the -- excuse me, excluded from the study as likely active smokers. About 2 percent of the study subjects, you'll see on the next slide under the line "Status of the completed analyses" this is from the prereport, about 1 percent of the lung cancer cases, 2 1/2 of the colon cancer controls and 2 percent of the population controls, or 2 percent overall, had urinary cotinine levels greater than 100 nanograms per milligram of

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creatinine, and that is certainly in the range where they might be active smokers rather than heavily passive exposed. The 2 percent number is very similar to, to the proportion of women in the 13 country international study that looked at women who were supposed to be lifetime, current non-smokers, about 2 percent of them also had elevated cotinines above 100 nanograms per milligram.

We tried other levels to exclude and it made virtually no difference in our study findings. The lower proportion of cases, there were actually fewer cases who were excluded than, than the other two, colon cancer controls and population controls, and that may well be because of the prior medical records screen; lung cancer cases were much more likely to have the information in their charts and to be removed from the pool early on.

Cotinine analyses are now complete for the entire study, a higher proportion of cases have no cotinine level that we were able to measure because we had next of kin respondents for about a third of the

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cases, but among all living study subjects equal proportions of cases and controls were willing to give us a urine sample and have it analyzed.

The extensive procedures that we took in this study to screen for tobacco use obviously don't guarantee that we have a pure lifetime non-smoker series, but they certainly serve to minimize the misclassification and we think it's, at the present time, the best that could be done. In addition to making sure all of our cases in the study had, were pathologically confirmed at the hospital level we requested slides so that one pathologist could review it just to make sure. Lung cancer is a disease that you want to be certain you're looking at primary cancers of the lung because risk factors for lung cancer are different than risk factors for colon, risk factors for breast cancer, and the lung is the site where many of these cancers metastasize to. So just because you've got a tumor in the lung doesn't mean it's necessarily a lung primary, so we had a very thorough review of the pathology for all of our cases,

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and we had to exclude 2 percent in this three year report and overall at the end of the study we excluded 1 percent of the total series because their pathology indicated that they were not primary lung cancers. But that's a very small proportion but we're quite sure that our lung cancer series is, in fact, primary carcinomas of the lung.

One of the goals of our study was to look at different kinds of lung cancer to see if there were differences in environmental tobacco smoke and not -- you can see here from the distribution that the only type of lung cancer that we have sufficient numbers of cases in the three report to look at was adenocarcinoma, over 75 percent of all the lung cancer cases in our study had adenocarcinoma of the lung and so we looked at all lung cancers combined and we looked at adenocarcinoma of the lung alone.

In this three year report we had a total of 420 lung cancer cases, we had 351 colon cancer controls and we had 780 population controls during the first three years of the study. You can see the distribution

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across the study centers about, slightly over 1/3rd came from the Los Angeles area, about a 1/3rd from the San Francisco Bay area and the remainder from the three southern study centers which were all smaller metropolitan areas; Atlanta, Houston and New Orleans. About 10 percent of our colon control group was next of kin, about 1/3rd of our lung cancer series was next of kin, and our population control group were obviously all living.

This slide looks at the estimated risk of lung cancer in non-smoking women associated with ever living with a spouse who smoked, and it was approximately 30 percent. if you look at the line that says all lung cancers for any type of tobacco exposure, when we compared our cases to our colon cancer controls the relative risk estimate was 1.28, when we compared it to the population control series the risk estimate was 1.29, quite similar. The estimates for adenocarcinoma alone were slightly higher than all lung cancers combined at that time.

We ran separate analyses for subjects who

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personally responded and or those for whom the information was obtained from surrogate respondents and next of kin and the findings were quite consistent. All the odds ratio in the paper and on these slides I'm going to show you today were adjusted for age, race, geographic region, the type of respondent, income and education. Other potential confounders including diet, occupational exposures and family history were not considered in this published three year report. Additional findings, however, from the data set were reported at the 1992 annual meeting of the American Society for Preventive Oncology, and the approximate 30 percent risk of lung cancer associated with ETS exposure shown here persisted after adjustment for dietary factors, vegetable consumption was the most significant food, family history of lung cancer and employment in high risk industries and occupations.

We also measured household radon in a sample of cases and controls, about -- excuse me -- under separate funding. This is an NCI funded grant. We measured radon levels in about 800 houses and radon

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levels are quite low in all the areas that we included in our study, fewer than 1 percent of the homes tested had levels of 4 microcuries or higher, and so the observed ETS associations in our published report are unlikely to result from confounding by these other factors.

This next slide, and I apologize, I don't think you have a hard copy of it, but it simply demonstrates a dose response. This slide shows pack years of ETS exposure and as you can see as exposure increases across the bottom the estimated risk tends to increase. This is for past years of exposure from spouse. We saw a positive dose response observed for all lung cancers as well as adenocarcinoma with several measures of spousal ETS including dose, duration and pack year.

This next slide looks at some other, the next two slides consider ETS exposure during adult life from various sources in addition to just the spouse related. Exposures to ETS from other household members on the job and in other activities in adult life, and here

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we'll call this, that social exposure, were associated with risks, elevations and risk of lung cancer.

For all lung cancers combined a history of ever being exposed in the house to a spouse or to their household members, the spouse is the top line and other household members shown after that, and if you'll look at the line for ever exposed you'll see that there is a non-significant 21 percent increased risk associated with ever living in a home with a spouse who smoked, a 23 percent increased relative risk associated with ever living in a house during adult life with other household members. And you can see that risks tend to increase as exposures increase.

Moving on to the next slide which considers workplace and social exposures, you can see that that same category of ever exposed as an employee in the workplace yields a significant 34 percent increased risk and a statistically significant trend associated with duration of exposure. Social exposure, that is not in the home and not while as an employee, was associated with about a 58 percent elevation in risk

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and also a significant positive trend. The confidence intervals, and that's the numbers that are shown in parenthesis after the odds ratios or the risk estimates, you'll see 1.34 and then 1.03 to 1.73, 1.58 and a confidence interval of 1.22 and 2.04. Those confidence intervals overlap and I'll go back, and they also overlap with these, and when that happens that, that means that because these confidence intervals all overlap we can't say that the 34 percent and the 58 percent are statistically significantly higher than the 21 or 23, even though the point estimates are certainly higher. The somewhat higher estimates in the workplace and in the social setting may reflect chance, may reflect some recall bias, or they may actually reflect a potential for a larger number of smokers and a larger number of smoke exposures that can occur in these settings compared to a home with a limited number of rooms and people.

This shows the association for childhood exposures, father, mother, and other household members during childhood, and we found no significant

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association to cigars, pipes, cigarettes or all types combined. Now these exposures are limited to exposures in the home during the first 18 years of life and after that exposures were attributed to adult life.

In summary, the findings of our study which included methods to evaluate recall bias, to minimize misclassification of smokers as non-smokers, to assure the accuracy of diagnosis and the classification of lung cancer and to adjust risk estimates for potential confounders are quite consistent with and extend the findings of the many published reports that were not able to address all these issues because they had fewer study subjects or more limited information. The overall approximate 30 percent increased risk associated with ETS exposure from smoking spouses is remarkably close to the 25 to 34 percent estimate in the evaluation of relevant studies in the 1986 report of the National Research Council, and it's somewhat higher than the 19 percent US estimate in the more recent 1993 EPA report. The significant positive dose response to exposure to tobacco within households and

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in the workplace and in social settings during adult life strongly supports the etiologic role of ETS in lung cancer in non-smokers, and the 34 percent increased risk associated with workplace exposures suggests the importance of this setting in the United States.

Thank you. Do you have any questions?

COMMISSIONER KOELLEIN: Thank you, Doctor.

MS. ELAINE PATRICK: Dr. Fontham, how did you assess the workplace exposures? How did you assess the workplace exposure, is that through the interview process?

DR. ELIZABETH FONTHAM: Yes. In the course of the interview -- I'll wait just a minute. Included in the interview each woman who participated in the study was asked about her lifetime work history starting with the first job she ever held and then the next and the next. We got where she was employed, what kind of work she did, whether it was a part time or a full time job, the number of years she was employed there and whether work exposures occurred in each of

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those workplace settings over a lifetime. Obviously it only had to happen once to be included in the ever exposed category; you can be exposed in one job and in no others that you were exposed. When we summed up years of exposure that included years of exposure across all jobs.

MS. ELAINE PATRICK: And this is independent of the spousal exposure? Is it an effort to assess the workplace exposure independent of the spousal exposure?

DR. ELIZABETH FONTHAM: Yeah, well the workplace exposure was --

MS. ELAINE PATRICK: Exclusively?

DR. ELIZABETH FONTHAM: -- exclusively workplace exposure. We, we have in subsequent analyses looked at workplace exposure adjusting for ever exposed to a spouse, ever exposed in social settings, and it actually changes the risk estimates very little.

MS. ELAINE PATRICK: Uh-huh. Okay.

COMMISSIONER KOELLEIN: Thank you, Doctor.

DR. ELIZABETH FONTHAM: Thank you.

COMMISSIONER KOELLEIN: Thank you for joining

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us.

MS. CAROLYN WEST: Call the representatives for Coalition of Smoke Free Maryland Workplaces.

MR. AL ERTEL: Good afternoon. My name is Al Ertel and I work as an engineer for General Electric in Rockville. I would like to present some of the views of the Coalition for Smoke Free Maryland Workplaces, of which I am Chair.

Our coalition includes employees from businesses ranging from a 1200 employee complex to an eight person law office, from a 600 seat restaurant to a Pizza Hut that sells beer over the counter. We have been filing complaints over workplace smoking with MOSH since 1991 and in 1992 filed a lawsuit against MOSH seeking a court order finding exposure to workplace smoking violates the existing general duty clause of Maryland's OSH Act. That lawsuit is now about to go to the Court of Appeals.

We're here today to support the proposed regulation as the right thing to do, but as I and Mr. Burkhart, a subsequent witness, will indicate, we

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suggest certain changes and clarifications should be considered. Specifically, we believe the provision allowing smoking rooms is unwise and should be deleted.

From our experience smoking rooms are unwise because, first, smoking rooms invariably leak ETS into non-smoking areas. As an example, for the 18 months General Electric had smoking rooms the stench within such rooms was so bad smokers frequently propped open the door. The janitors did the same thing for several hours at night before cleaning, with other employees still in the work area. I would add GE's smoking rooms had the 60 cubic feet per minute per smoker external air exhaust rate the ASHRAE comfort standard recommends and they were negatively pressurized, yet still we had problems.

Second, smoking rooms create a MOSH sanctioned hazard to the smoker themselves. MOSH has found ETS is a hazard, that's environmental tobacco smoke. When a smoker goes into an enclosed room where others are smoking that smoker is exposed to ETS. Maryland's OSH Act specifically says a worker cannot

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waiver or be required to waiver their rights to protection from a hazard.

Third, smoking rooms create an enforcement problem; for example when General Electric and other businesses that we're involved with used such rooms as a transition before finally going smoke free they found some smokers took the attitude "If I can smoke in the smoking room I'll just close the door to my office and smoke." Or, "If I'm not a boss with a private office I'll sneak a smoke in the bathroom." But after a fire due to careless smoking caused evacuation of an 8 story office building GE finally went smoke free and the enforcement problems stopped. We had a simple rule; no smoking in the building.

Fourth, smoking rooms also undercut one of the benefits noted by the Johns Hopkins study, that going totally smoke free helped push 25 percent of Johns Hopkins smokers to finally stop smoking, as well as reduce fires from 20 a year to zero. At GE when the smoking rooms were eliminated about 1/3rd of the remaining smokers finally stopped smoking.

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Fifth, smoking rooms open the regulation to mischief. As worded, the regulation does not restrict the use of smoking rooms to the employees of the employer, and we don't think that so long as such rooms are allowed one is going to be able to restrict who uses them. We thought it significant that at the January MOSH Advisory Board meeting where smoking rooms were discussed that Board member Behringer offered this concern based on the 8 years his company struggled before finally going smoke free.

Sixth, and last, smoking rooms are inconsistent with the State's own policy. Governor Schaefer's Executive Order banning all indoor smoking in September 1992 did not allow for smoking rooms and janitors who work in MOSH's own building have been protected. Under the Court of Appeals Order issued by Chief Judge Murphy in November of 1992 the same is true of all judicial facilities throughout Maryland.

We believe there is a real ethical issue in excluding people who work as janitors from full protection from ETS. Just because they are not in the

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most elitist jobs does not make them less deserving of protection. Allowing smoking rooms would perpetuate risks to many employees, but especially a largely minority staff employed as janitors, in order to minimize inconvenience to a largely white population of smokers. As a Coalition with members with a diversity of backgrounds we believe the smoking room provision is unfair and unwise.

Mr. Commissioner, Governor Schaefer has banned smoking rooms, Chief Judge Murphy has banned smoking rooms, our Coalition agrees with these leadership positions and asks MOSH to respectfully consider banning smoking rooms. Thank you.

MR. KEITH BURKHART: Hi, my name is Keith Burkhart, I live in Owings Mills, Maryland. I am a, excuse me. I am a former restaurant waiter who left the occupation because of health problems and concerns over exposure to smoking in the workplace. I really appreciate this landmark regulation.

When I worked at restaurants I used to leave work with a sore throat and burning eyes and clothes

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smelling of tobacco smoke. Even though the money was good it was not worth the risk to my health. One of the waitresses was a woman who only had one lung. She would have liked to have quit too, but then again the money was good and she needed a job. Now with this new regulation banning smoking in restaurants and bars and all other workplaces we don't have to choose between our jobs and our health. It opens up the opportunity for me to go back to working in a restaurant or a bar. The extra money will help in paying my expenses as I go to college part time.

Also, based on my experience and observations, I would suggest the language of the regulation needs to be clarified in several places:

First, the definition of enclosed workplaces specifically should lift parking garages and the common areas of apartment buildings. These are really enclosed workplaces for parking attendants, delivery people and maintenance people. I am also aware of several fires started in such areas by careless smoking.

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Second, the propose regulation says smoking is not allowed in a vehicle when an employee uses it in the course of business and the vehicle is occupied by more than one employee. But that language inadvertently allows smoking in a vehicle when only one employee but several non-employees are present. I would suggest the language be clarified to clearly cover a vehicle, quote, "When an employee uses it in the course of employment and it is occupied by more than one individual."

Third, I would also suggest the language of the regulation needs to be clarified to ban smoking on the patio or deck areas of restaurants and bars. I am submitting as an exhibit the February 12th, 1993, position statement on smoking by Paul Kreuzburg, President of the Maryland Restaurant Association. I and my friends who work in restaurants and bars strongly agree with the Association's position favoring a ban on smoking on patio or deck areas. Quote, "Again, if it's uncomfortable indoors it can't be much better outdoors for the person sitting or the employee

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working nearby, and how do we define outdoors? Does a canopy over a patio make it outdoors or indoors? Besides, we're concerned that allowing smoking in the outdoors area of a public place could set up new conflicts between smokers and non-smokers."

I think this is a courageous leadership position the Maryland Restaurant Association has taken and it shows that they really care about their employees and customers.

I would ask those restaurant and bar owners who oppose this regulation to include in their comments why are they ignoring the well known health risk to their employees and customers, including young children and infants, from exposure to smoking. How ethically can opponents of this regulation ignore the overwhelming medical evidence of the hazards?

Please consider these clarifications to the regulations. Thank you for the opportunity to comment and for trying to do the right thing, and this regulation makes me proud to be a citizen of the State of Maryland. Thank you.

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COMMISSIONER KOELLEIN: Thank you.

MS. GAIL EHREN FRIED: Yeah, hi, my name is Gail Ehren Fried and I'm a resident of Mitchelville, Maryland. I'm in attendance today on behalf of family and friends employed by the private sector in which smoking control is at a minimum. These individuals do not want their names mentioned nor do they want to testify in hearings of this nature for fear of losing their jobs and they hope that the regulations to curb smoking in the workplace will soon be a reality. I would like to tell you something about these people and what their workplace has exposed them to.

My son, 21 years old, is employed by a restaurant which seats 125 to 150 people. Tobacco smoke is present most of the time, most often while in the workplace he encounters frequent bouts of sinus congestion, watery eyes, sore throat and headaches. This makes it very difficult for him to perform to his maximum. Medication has not been very effective in relieving these symptoms. He wants to keep his job because it offers him flexible work schedule and

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provides him an adequate income. He does not know how long he can tolerate the smoking environment and hopes that regulation will pass a law to make it smoke free in the very near future.

My daughter in law is a waitress for a restaurant which seats 75 people. Frequent asthma attacks have occurred at work, her doctor wanted to know if she was being exposed to tobacco smoke, and according to him tobacco smoke will aggravate these attacks. He placed her on medication but the medication was very expensive and it also hindered her job performance. A few months ago she learned that she was pregnant so she can no longer take the medicine because it can possibly harm her fetus. Therefore, she has no choice but to terminate her job. The doctor feels that once she is out of the smoking environment her asthma attacks will cease. If the workplace had been smoke free she could have continued to work without any risk to her or the fetus, and termination of the job will produce a hardship because she needs the extra income.

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For years my mother was a practicing beautician where she had her own salon at her home while she was raising her family. She did not allow smoking and after her family was raised she closed her salon. My dad became ill and died which necessitated her to return to work, at this time for someone else. She needed the money and the independence but this was quickly lost when she developed health problems that were severely effected by the tobacco smoke in the workplace. Recurring sinus irritation and congestion began to interfere with her productivity. After a few bouts with respiratory and circulatory problems it was discovered that her arteries were becoming very narrowed and her doctor felt that the smoking environment was promoting the arteries to constrict even more. She terminated her job to avoid more serious health problems and income and independence was lost.

A friend of mine who works for a bowling alley, she is not a smoker and many of the employees are, there is not a designated smoking area and the

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employees are free to smoke as much as they want to. Tobacco smoke exposure is constant. She likes her job but wants to see regulation pass a law to protect her rights as a non-smoker. Some of us have contacted the bowling alley to request restrictions on smoking and at this point I would like to quote to an excerpt from a letter that they responded with, and this is on July 26th, 1993, and they said "Hopefully in the near future all public places, by law, will be smoke free. This would eliminate our involvement as to being biased to smokers or non-smoker's rights." So as you see they did not even give me an answer about designated smoking areas.

Okay, the, by the same token there are many small restaurants in the area that have basically said the same thing, that when this became law that they would abide by it but until then there was nothing they could do.

To sum up all the situations I really ponder the question why do we strive so hard to keep our younger generation, teenagers, senior citizens,

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pregnant women, away from the smoking environment? Most importantly we're asking them not to indulge in tobacco smoke; however, it's almost hypocritical because here we are exposing these people to second hand smoke in their workplace, and it has been drove into their heads that to smoke is not good, but it's acceptable to inhale second hand smoke in a place of employment.

You know, we discourage abortions yet we aren't controlling the tobacco smoke that pregnant women are exposed to in the workplace, which also jeopardizes the life of the fetus. Senior citizens are becoming more employable and many have health problems but these health problems do not show up until they have substances that are aggravating their conditions such as tobacco smoke, and I'm wondering if we can use that old term "Occupational hazard" or do we fight to prevent this exposure? Employees are a genuine asset and they really must be protected.

In closing on behalf of my family and friends I would like to thank MOSH for tackling this very tough

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issue and hope you will implement as comprehensive and across the board ban, smoking ban as possible. And I do thank you for letting me speak today.

COMMISSIONER KOELLEIN: Thank you all.

MS. CAROLYN WEST: Commissioner, I'd just like to enter the remarks of, the testimony of Mr. Ertel as Exhibit 132 and the documents by Mr. Keith Burkhart as Exhibit 133.

(The documents referred to as Exhibits 132 and 133 were marked for identification and received into evidence.)

MS. CAROLYN WEST: I call Mr. James Repace.

MR. JAMES REPACE: Commissioner Koellein and Counselor Patrick, it's a pleasure to be here. My name is James Repace, I am a physicist with the Environmental Protection Agency; however, I'm appearing here in my private capacity as a scientist who has published 38 papers on environmental tobacco smoke in the pertinent scientific literature. I have lectured extensively on this subject at such universities as

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Harvard, Yale, Johns Hopkins, University of California San Francisco, and Stanford University as well as several foreign universities.

I'd like to discuss basically four issues which would expand on my testimony which I gave on December 16th before the MOSH Advisory Board. First I would like to say that the regulations which have been proposed by the State of Maryland are, in my professional opinion, scientifically defensible both with regard to risk assessment of environmental tobacco smoke and risk management of environmental tobacco smoke. There is no question in my mind that environmental tobacco smoke causes both lung cancer and heart disease in non-smokers, that the workplace is a significant source of environmental tobacco smoke exposure, and as far as the risk management is concerned prohibiting workplace smoking will certainly protect non-smokers from environmental tobacco smoke. I believe that the separately ventilated areas that are proposed by the State are a good first step, but there are data which indicate that it is very difficult to

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make separately ventilated areas contain the tobacco smoke and I think you're going to have some enforcement problems unless there are rigid specifications as to how those designated smoking areas are going to be built and operated. Even if they're designed properly they can often get out of balance and leak, and the State of California, particularly the County of Sacramento, has made measurements on very well designed designated smoking areas and has found that they do leak, and I have evaluated the leakage on those and found that there are considerable risks associated with that leakage, so that is going to be a problem.

The second issue that I would like to discuss is that of the tobacco industry's criticism of both what the State is doing on environmental tobacco smoke and also on my previous testimony which was criticized in Exhibit number 49 in a briefing book on environmental tobacco smoke submitted by Mr. Bruce Bereano on behalf of the Tobacco Institute. This is about a quarter of an inch thick and most of it is devoted to criticizing my work and I feel as long as

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this is going to be a public record that I should respond at least in part to what they have said and I am submitting a detailed rebuttal of their comments. I just want to summarize a few points:

The Tobacco Industry testimony, particularly that of Mr. Simon Turner and Dr. Larry Holcomb, confuses exposure and dose. It is contradicted by their own data on the variability of the RSP to nicotine ratio from environmental tobacco smoke. The dietary cotinine is not a compounding factor for, dietary nicotine is not a compounding factor for cotinine body fluids unless you happen to be a bovine and eat your weight in nicotine containing vegetables such as eggplants, tomatoes and potato skins. The, Dr. Holcomb's paper on RSP levels from environmental tobacco smoke ignores key studies and misquotes some other key studies, it is not credible science in my opinion. The, the position of both Mr. Turner, Dr. Holcomb and the Tobacco Institute is in opposition to the conclusions of the Environmental Protection Agency, th National Research Council, the Surgeon General and

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the Public Health Service and the International Agency for Research on Cancer on the utility of cotinine as a biomarker for environmental tobacco smoke.

And, finally, with respect to my own work their criticism ignores the validation of the Repace and Lowrey pharmakinetic model relating ETS exposure, dose and risk.

Can I have the next slide, please? Now I'd like to devote the remainder of my testimony to a single issue, and that is the question of whether environmental tobacco smoke exposures in Maryland workplaces exceed significant risk for cancer and for heart disease. Now I know that the report of the hearings concluded that the State of Maryland did not have to conclude that there was significant risk for environmental tobacco smoke in the workplace, and as a non-lawyer I found their arguments persuasive; however, let us assume, arguendo, that the tobacco industry is correct and we do have to prove significant risk. I looked at this issue theoretically first and I developed an equation which is given on the top of this

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slide for, I guess this is -- here it is. For ETS cancer risk, and it basically says that for a ratio of smoker density to air exchange rate of 1 you have about a 3 per thousand ETS lung cancer risk. And if one plots typical values for smoker density and air exchange for places like office and workplaces you can calculate that the ETS lung cancer risk for working in a typical office is almost 3 per thousand. So it is almost three times the significant risk level as defined by OSHA. The heart disease risk is about an order of magnitude greater than the lung cancer risk so that would be nearly 3 per hundred. So there is no question in the non-industrial workplace that you have significant risk for both cancer and heart disease.

Now in the typical restaurant the situation is even worse. If you have just a little bit over quarter occupancy in a restaurant the workplace ETS lung cancer risk for non-smoking workers would be 1 per thousand, that's at quarter occupancy, and the heart disease risk would be 1 per hundred. So there's no question whatsoever that even if the tobacco industry

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is correct and that the State of Maryland must demonstrate significant risk that significant risk pertains, and this is on a, on a theoretical basis.

Now, is there any data which would support what I've said? Can I have the next to the last slide, please? Now this is data which plots the respirable particle concentration as function of the number of burning cigarettes per 100 cubic meters, and 100 cubic meter space volume is something of the order of let's say a room which is 20 by 25 with an 8 foot ceiling. And these data points here, all but three of them were taken in the State of Maryland, and you can see these dotted rating lines correspond to the calculated air exchange rates. Now the American Society for Heating Refrigeration and Air Conditioning Engineers specifies air exchange rates for buildings in the local area, in the Baltimore-Washington area that's adopted under the BOCA Building Code. And that specifies typically from about .8 air changes an hour in an office to as much as 7 air changes an hour in a restaurant. And that's assuming that these places are actually operated

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according to code. They are designed according to code but often the ventilation rates are observed in a breech. But, nevertheless, you can see that they all, all the ventilation rates do fall in the range of roughly 1/2 to 7 air changes an hour.

Now I did a calculation of the lung cancer risks, assuming a 25 micrograms per cubic meter, 9 ETS background. Significant risks then were obtained for all tata points which are 92 micrograms per cubic meter or more, where you can see that every single data point for finite smoker density exceeds 92 micrograms per cubic meter. So in every single one of these places you would have a significant risk for lung cancer, and remember that the heart disease risk is 10 times as great, so that we're talking about 9 micrograms per cubic meter would correspond to a heart disease risk of 1 per thousand.

So there is no question both exponentially and theoretically that you are totally justified in assuming that there is a significant risk of 1 in a thousand in Maryland workplaces.

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Now these data I point out were taken at a time when smoking prevalence nationally was about 33 percent, currently it's about 27 percent in the State of Maryland, but you can easily see given the massive violations of significant risk that the small difference between those two numbers is not important.

And I'd like to make one final comment, in listening to Dr. Jenkins' presentation on the Oak Ridge data I heard that presentation when it was given to the US Occupational Safety and Health Administration in Washington, and one of the questions that was raised in my mind without looking at the data is that if you accept it completely at face value, and I have no reason to doubt that it's accurately measured, the real question is are the, the people who are sampled representative of the US population? And it was very clear from comparing the distribution, the demographic distribution of the people that were sampled in that study that a great many of them were high socioeconomic status women. We know from the California activity pattern study that high SES women tend to have very low

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exposures to ETS; in fact the data that Jenkins and all are reporting to me it looked like they were about two orders of magnitude lower than you would expect for typical workplace exposures, so I believe that they are not representative of the national population.

And a comment on Dr. Aviado's testimony, Dr. Aviado may be a very fine pharmacologist but I don't think he knows much about OSH PEL's and POV's. Those cannot be taken as in isolation for a mixture of chemicals like environmental tobacco smoke; you have 4700 chemicals in ETS and you can't take them one by one and say "Well, TLV is not violated here, we'll throw that away, second one TLV is not violated here we'll throw that away." When you're dealing with a mixture you have a combined TLV and you have to add them up. So his statement is completely nonsense.

I'd be happy to answer any questions.

MS. ELAINE PATRICK: I have a couple, Mr. Repace. Your, your slide (Banging obliterates voice) interested me, the expression. What does that mean?

DR. JAMES REPACE: That means that both Dr.

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Holcomb and Mr. Turner said when we considered exposure to environmental tobacco smoke we did not consider the deposition of tobacco smoke particles on the surface of the lung, which is 11 percent of what the lung is exposed to, and that is correct. But when you calculate risk you, if you do it from an exposure/response relationship you multiply the exposure/response relationship times the exposure, and if you do a dose/response relationship, which Dr. Turner and Dr. Holcomb seem to be saying we should do, they're saying we should multiply the exposure by 11 percent. Well, if you do then you have to multiply the exposure response by 11 percent and you get the same resultant risk, so they have just said you only multiply one term in the equation by 11 percent when in fact you have to multiply both. So what they have said essentially about us ignoring the fact that tobacco smoke is, is not 100 percent absorbed is just wrong.

MS. ELAINE PATRICK: Did you also submit written testimony today?

DR. JAMES REPACE: Yes, I submitted an eight

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page written testimony, and with regard to the rebuttal to the Tobacco Institute's Exhibit number 49, I only have brought one copy of that with me because I couldn't get to a copy machine, but I'd like to enter that into evidence today.

MS. ELAINE PATRICK: Do you have copies of your overheads to submit to the record or can you send to --

DR. JAMES REPACE: Yes, I do have extra copies of my overheads with me.

MS. ELAINE PATRICK: Okay.

DR. JAMES REPACE: I will so submit those too.

MS. ELAINE PATRICK: Okay. Now going back to your overhead that showed, it appears like the third one, the second one. The 2 per 100 per CAD?

DR. JAMES REPACE: Is that the one?

MS. ELAINE PATRICK: No. Will you walk through that formula again please? The ETS cancer risk equals 3.24. Is that, is that your pharmakinetic model that you worked on --

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DR. JAMES REPACE: No, that is based on the atmospheric concentration of, of the particulate matter in the air from environmental tobacco smoke. In 1985 Dr. Lowery and I published in the New York State Journal of Medicine an exposure response relationship which allowed us to associate a given risk level with a given level of environmental tobacco smoke particles in the air, and we found that 3/4 of a microgram of ETS particulate matter per cubic meter corresponded to a 1 to 100,000 lifetime risk assuming a 40 year working lifetime. Now OSHA used the 45 year working lifetime so we've adjusted this formula to take that into account. And so what we did was to, to give the risk as a function of the ratio of the smoker density to the air exchange rate, because in any workplace what's important in determining the non-smoker's exposure is the density of smokers, and the average smoker smokes about two cigarettes an hour over a 16 hour day. So the smoking rate is general, can be taken as a constant and so the only issue is how big is the space, so you'd have to normalize for that by dividing the number of

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smokers by the room volume. And then you take and model the workplace, and we know the occupancy of a typical office is about 7 persons per 1,000 square feet, and at a 27 percent smoking prevalence that works out to about 1.9 smokers per 1,000 square feet. You assume a 10 foot ceiling and then so you've got the smoker density.

Now you divide that by the air exchange rate but we know the air exchange rate for offices and for restaurants is specified by the building code, so we add a hypothetical office and a hypothetical restaurant which are typical with code specified occupancy, code specified ventilation and we simply multiply that by the conversion factor which translates ETS particulate matter which is given by our model into a lifetime lung cancer risk, and you wind up with an estimate of what the lung cancer risk is.

Now the American Heart Association has reported that there are about, there's 10 heart disease deaths for every lung cancer death, and so we simply multiply -- this is a crude way of doing it, but this,

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we simply multiply the cancer risk by a factor of 10 to get an estimate of the heart disease risk. And so this is the way we get the typical cancer risk and the typical heart disease risk for a non-industrial workplace.

Now I should say that these do not represent the most exposed individuals, the most exposed individuals according to our model would have 10 times this exposure, so you can see that those individuals would have the very high exposure and the very high risk indeed.

I've given the details and the variation of this in my written testimony and if you should require any amplification on that this is all published material, I'd be happy to amplify on it.

COMMISSIONER KOELLEIN: Thank you, sir.

DR. JAMES REPACE: Thank you.

MS. CAROLYN WEST: Commissioner, the testimony of Mr. Repace together with the rebuttal and the copies of the overhead presentation have been marked as Exhibit number 134.

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

(The document referred to as Exhibit 134 was marked for identification and received into evidence.)

MS. CAROLYN WEST: Now call W. Miles Cole.

MR. W. MILES COLE: Good afternoon, Commissioner, my name is Miles Cole and I'm representing the Maryland Chamber of Commerce and its 1600 members. We, as employers, share your concern for the health of employees and for the work environment; however, we object to the proposed regulations prohibiting smoking in enclosed workplaces which are before you today. We feel that the legislature considered this issue and the legislature didn't act, we feel that this is an abuse of administrative powers to enact such broad and sweeping regulations of smoking in the workplace in light of the legislature's enaction.

Employers are also concerned about the impact of, on employers having to enforce this law and being subject to, to fines. As we see the law we get 7,000

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per occurrence. There are a lot of issues, workplace issues that will result in trying to enforce this law we feel need to be clarified before any further regulation.

Also speculating about the proposed regulations there is concern about whether or not employers would be involved in the unemployment laws for having to pay compensation for an employee who is fired as a result of violating the non-smoking rule? Likewise there is concern whether or not the Maryland Human Relations Act could be construed to create smoking as a protected class and therefore discharge could be a violation of Civil Rights. These issues need to be discussed, they're sort of speculative issues but they're issues that people have raised.

Initially there was concern raised about the definitions, the, does the regulation mean that if I employ someone to clean my house that we can't smoke in my house while that person is in the house? Does this mean that if there's a repairman in the house that we can't smoke while the repairman is in the house?

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

Likewise does the regulation completely bar smoking in hotels because hotels are a workplace? Does this mean that a tourist who comes and stays in a hotel in Downtown Baltimore is prohibited from smoking because it is a workplace?

We feel that you should reconsider these regulations and this is a matter of clear public policy which the legislature has considered and decided not to act. Thank you very much.

COMMISSIONER KOELLEIN: Thank you, Mr. Cole, thank you.

MS. CAROLYN WEST: Keith Hamby.

MR. KEITH HAMBY: Good afternoon. My name is Keith Hamby. I am here today first and foremost as a concerned citizen; secondly I am employed by the State of Maryland as a correctional officer-sergeant at the Maryland Correctional Training Center in Hagerstown. I have worked there for 12 years. I also am a smoker and have been for approximately 14 years.

Now knowing that I am a smoker many of those present today may feel that I'm here to speak against

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this proposed regulation, yet I do not oppose nor favor this proposal. I do rise to ask that a sense of fairness be applied here. I do speak for equal rights. Let me explain further.

As I am an employee of the State of Maryland I have not been permitted to smoke inside any building at my workplace since October 1st, 1992. This was when the ban on smoking in any state, Maryland owned building was implemented by Governor Schaefer signing an executive order of 1992.20, Executive Agency Policy on Smoking. As a correctional officer-sergeant I work first hand with inmates, those incarcerated by the State of Maryland. I work exclusively in inmate housing units, areas where inmates are allowed to smoke. Specifically, inmates are permitted to smoke in their immediate living areas.

One type of living area is an individual or double bunked cell. There are approximately 170 cells in each housing unit. The large exhaust fans in the hallways outside these cells pull the smoke from the cells into the hallways and other common areas of the

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building; areas which are non-smoking areas even for inmates. Part of my daily duties include the counting of inmates in my assigned area. This is accomplished by looking in each cell, making sure each inmate is accounted for. On many an occasion I've had smoke blown in my face through a cell door window. This is not necessarily done on purpose, the fact being that even some smoking inmates don't like their cells filled with smoke.

Another type of living area is the dormitory type setting, also known as a quonset hut. This is an open building with no barriers between the 124 double bunked beds spaced approximately 5' apart. When working these areas I must frequently enter them to conduct inmate head counts and security checks. The exhaust fans utilized in these areas only circulate the smoke throughout the building before exhausting into the outside air. The smell of tobacco smoke permeates the air in all areas of these inmate housing units.

Once again, I, as a state employee, am not permitted to smoke anywhere inside these buildings.

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Knowing all of this I present this question today: Is the State of Maryland telling me that my second hand smoke is harmful to my coworkers and inmates aline yet inmates' second hand smoke is not harmful to my coworkers and me?

Governor Schaefer has stated publicly that he has not submitted cigarette tax increases in his proposed budgets to generate additional revenues but to encourage those who smoke to quit smoking due to increased financial burden. This may even be the reason that may force me to quit smoking. Yet even if I quit smoking today tomorrow I must go to work in a smoke filled environment. Knowing at least my addiction to cigarettes would this aide me in my attempt to quit smoking? Would I be a healthier person six months later? I suggest not on both accounts.

As Alcoholics Anonymous meetings are not held in places were alcoholic beverages are served or sold neither should the State of Maryland ask their employees to not smoke or attempt to quit smoking and enforce them to smoke in a smoke filled environment.

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To this point in time the State of Maryland has chosen to exempt certain classes of citizens from their present policy, versus exempting certain classifications of building uses. This is what I refer to when I speak of fairness and equality in regards to this issue.

The present policy utilized by the State of Maryland is totally biased and possibly discriminatory. I would hope that any action taken in the future by any branch or segment of Maryland State Government would correct this inequity.

On this issue the State of Maryland does not have their own house in order. How can they then attempt to dictate to their own citizens and business owners how they should keep theirs?

Do not turn back the hands of time and once again let government enact laws and policies that exclude certain classes of citizens; treat all fairly and equally.

Finally, I must repeat that I neither speak for or against this proposed regulation. I only ask

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

that whichever way it turns out fairness and equality be applied to all those involved, regardless of what class of people they may be.

Thank you. I'd be happy to answer any questions.

COMMISSIONER KOELLEIN: Thank you, sir.

MR. KEITH HAMBY: Thank you.

MS. CAROLYN WEST: Commissioner, I'd just like to indicate that testimony by Mr. Cole has been marked as Exhibit 135 and the testimony by Mr. Hamby has been marked as Exhibit number 136.

(The documents referred to as Exhibits 135 and 136 were marked for identification and received into evidence.)

MS. CAROLYN WEST: I now call on Dr. Daniel Ford.

MS. ELAINE PATRICK: Not here.

(Brief off the record discussion.)

MS. CAROLYN WEST: Then I call on R. Chris Jeffries.

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MR. R. CHRIS JEFFRIES: Commissioner. My name is Chris Jeffries, I have the Red Horse Steak House which is located in Hagerstown, Maryland. I don't know if you're familiar with that portion of the state, it's kind of far from here but we have a building located about ten minutes from the Pennsylvania Line and approximately 10 minutes from the West Virginia line.

I brought a book along, which is a visitor's register, and I've marked some of the local, within a half hour driving range, that are out of state. And as you can see they're highlighted in the orange, and this is just a small unsolicited sampling of my business.

MS. ELAINE PATRICK: These are out of state - -

MR. R. CHRIS JEFFRIES: These are out of state within 10 minutes to a half hour distance. And we've heard testimony from Restaurant Association in Maryland which I'm also a member, that regulating this throughout the state would give us a level playing field. That's not the case in my case. We've also heard that 70 percent of the population does not smoke,

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

so that means one out of four persons, so if I have two customers, every time I get two customers at least one of those couples is going to smoke. And to ban that is not regulating, banning it leaves nothing to regulate. I don't think this is creating a very good economic impact for Maryland; Maryland already is rated like the third worst state in the country to do business, I think is drawing us down further to number one which I personally don't want, I live here and I would hate to see that.

On the economic side of this, 70 to 80 percent of my business is from out of state so if 30 percent of those people smoke that leaves 20 to 24 percent of my out of state business are smokers, and I'm, I've been in this business for 20 years and have worked hard to build the business and I'd hate to take a chance of losing 20 percent of it for a regulation banning smoking in the workplace. I'd rather see it regulated and controlled, not an outright ban.

Another comment from the floor, from the Restaurant Association of Maryland, was that he quit

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smoking and his sales receipts increased. Well I've offered non-smoking area and have offered a smoking area and my sales also increased so there's not really a big difference there.

And my own point is with all this information that I've seen today, possibly it'd be a good idea to ban smoking in the workplace but not just in Maryland. Maryland has a lot of state borders and a lot of business is generated close to these borders and it's going to create an unfair competition trying to compete with other states that allow smoking for that 24 percent of my customers that do smoke. Thank you.

MS. ELAINE PATRICK: Mr. Jeffries, I just have a couple of quick questions. You have both a non-smoking and a smoking area right now. How do you, how big is your restaurant, how many seats do you hold?

MR. R. CHRIS JEFFRIES: I have approximately 100 seats in the non-smoking room, separate room, and I have 60 some seats in the smoking room.

MS. ELAINE PATRICK: And are they used in about an equal percentage? Is there greater demand for

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one area or the other?

MR. R. CHRIS JEFFRIES: Pretty much equal.

MS. ELAINE PATRICK: Pretty much equal. And those non, those non-Maryland people who come to your restaurant, it must be a steak house I take it from the name of your restaurant.

MR. R. CHRIS JEFFRIES: It's a steak house and dinner, we're only open from 4:00 to 10:00 p.m.

MS. ELAINE PATRICK: 4:00 to 10:00, you open every night, or --

MR. R. CHRIS JEFFRIES: Every night.

MS. ELAINE PATRICK: And do you have a lot of repeat business?

MR. R. CHRIS JEFFRIES: Lot of repeat business. I get people from Canada, see them twice a year, see them on the way to Florid and on their way back to Canada and they plan their trip to stop there.

MS. ELAINE PATRICK: Uh-huh. And why do they stop off at your place?

MR. R. CHRIS JEFFRIES: I guess they like the food and the hospitality. As a business person my

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

major concern is economics, and I take every step, measure to please both smokers and non-smokers, and if my business would dictate to me that people don't want smoking then I would, I would quit it on my own, I don't need to be regulated for that.

MS. ELAINE PATRICK: And do you know what percentage of the people that you show of your restaurant, what percentage of those people aren't smokers?

MR. R. CHRIS JEFFRIES: I work 14 hours a week and I don't have time to survey like that.

MS. ELAINE PATRICK: How about in a day?

MR. R. CHRIS JEFFRIES: Today I found out about 70 percent of the population so I would say about 70 percent.

MS. ELAINE PATRICK: That -- Have you ever talked to any restauranteur that's gone smoke free? The fellows that were talking this morning, that --

MR. R. CHRIS JEFFRIES: No. I know they did it at McDonald's but it's a different type of atmosphere, you might have somebody for 30 minutes in

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McDonald's but my customers spend an average of two hours.

MS. ELAINE PATRICK: Two hours on the average?

MR. R. CHRIS JEFFRIES: Uh-huh.

MS. ELAINE PATRICK: But you haven't talked to anybody about, who operates a smoke free restaurant like yours about --

MR. R. CHRIS JEFFRIES: No, I haven't. I did talk to some of my customers that do smoke, in particular some people from Winchester, Virginia, and they say that the majority portion of their meal setting there, afterward is having a drink and a cigarette, and if they couldn't smoke it would have an impact.

MS. ELAINE PATRICK: How far is it to Winchester?

MR. R. CHRIS JEFFRIES: One hour drive.

MS. ELAINE PATRICK: So they come a whole hour just for your restaurant?

MR. R. CHRIS JEFFRIES: Uh-huh. That's correct.

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

MS. ELAINE PATRICK: Thank you.

MS. CAROLYN WEST: Call Robert Resh.

COMMISSIONER KOELLEIN: Thank you.

MR. ROBERT RESH: Hi. My name is Bob Resh and I'm President of the Washington County Beverage and Restaurant Association. Our organization encumbers both restaurants, licensed beverage establishments, bars as well as liquor stores, and I'm also a member of the Restaurant Association of Maryland, and I have to say that I'm completely in opposition to their more recent changed position. It is not supportive, at least not supportive of most restauranteurs that I know.

I wanted you to look at the first one there on the table, 7. This is taken from "Smoking in Restaurants; A Consumer Attitude Survey." This was published in February of '93 from the National Restaurant Association Research Department, and what it's showing there is that if smoking was banned in all restaurants would it affect how often you eat away from home, would you eat at restaurants more often, about

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the same or less often? As you can see, if you look at the first column there that offers for consumers 10 percent would eat out more often, 73 percent about the same, and 16 percent would eat out less often. So that looks as though it's conflicting data of what they were representing earlier today.

If you'd look at the other table that I offered to you, "Operating Essentials Regarding Smoking Bans by Average Check Size," you can see that on a less than $8.00 a check average a restauranteur feels very strongly that his business would be hurt, 8.00 to 14.99 almost the same amount, and as you get higher up the scare -- scale, excuse me, higher up the socioeconomic ladder you can see where that declines.

Furthermore, as Chris Jeffries earlier indicated, in Washington County we have a very interdependent economy with West Virginia and Pennsylvania; less than 10 miles in some areas. People can drive to whatever restaurant of their choice, so if it's not, if it's not a regulation that includes all states it would certainly put us at an economic

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disadvantage. It's also a contradiction to tourism and promotion. People from out of state who would be certainly unaware of such a regulation would come into our state for whatever reason, if they are a smoker would very well likely to choose to go to a neighboring state.

Another point I'd like to make is that the stoppage of smoking is already happening on its own. No regulation is necessary; in my restaurant alone I'm ever expanding my non-smoking section. Without question, five years ago there were more smokers than there are today. And preceding five years from that there also were more, so my hunch would be that five years from now there would be even less smokers.

Currently there's peaceful coexistence between smokers and non-smokers. If you were to impose a regulation absolutely you would be imposing chaos; there would be someone who would get mad, someone who would be extremely upset. In Washington County only two restaurants that are full service sit down restaurants currently are completely smoke free.

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You've been asking questions earlier I heard regarding whether that's hurt or helped their business: One, it's too new to say on that because I know this individual and his restaurant just began in January to be smoke free, prior to that there was a restaurant that opened smoke free so there'd be no history one way or another with that particular restaurant. And with the issue of smoking in the workplace and the belief that exposure to secondary smoke in the workplace is unhealthy, what's really unhealthy is a worker with no place to work, a displaced worker, and if in fact we were to lose 16 percent of our business due to this regulation certainly there would be some layoffs.

With that said I'd also like to point out my restaurant has 55 employees; 8 of those 55, I'll offer this to you, 8 of those 55 are non-smokers, which means 85 percent of my employees smoke. So with this regulation being imposed supposedly to protect workers in the workplace I ask with these kind of numbers whom would we be protecting from whom?

COMMISSIONER KOELLEIN: Thank you.

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

MR. ROBERT RESH: Questions?

(Tape 4)

MS. CAROLYN WEST: Commissioner, I'll mark his exhibit as 136, 137, and call on David R. Finn.

(The document referred to as Exhibit 137 was marked for identification and received into evidence.)

MR. DAVID R. FINN: Good afternoon. My name is David Finn, from Hagerstown, and I'm an attorney with the Baltimore firm of Titus and Rosenberg. I'm here on behalf of Tobacco Technologies Incorporated, which is a company located in Finksburg, Carroll County.

Tobacco Technology is in the business of manufacturing flavoring for tobacco; they take raw materials and blend them with tobacco to produce flavored tobacco and essence. Tobacco Technology has approximately 15 employees and does a national business as well as international business, exporting its flavorings to many countries.

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As part of the business, or part of the requirements of such a business is that the product needs to be tested, and Tobacco Technology has a few employees that, among other things, test essentially the finished product; they have to smoke to see if the flavoring has been done correctly. This, this regulation would have a significant impact on Tobacco Technology if it's employees were unable to test the product. So I am here to request a similar exclusion to the exclusion granted to tobacconist establishments, and essentially that exclusion would be an exclusion for companies for smoking that is required or necessary for the conduct of a tobacco related business; it's a limited narrow exclusion and one that we think appropriate in this case.

MS. ELAINE PATRICK: Did you bring any language with you --

MR. DAVID R. FINN: No, I haven't. I brought some notes but I haven't formally drafted any language. I could do so as soon as I get finished --

MS. ELAINE PATRICK: Let's hear your

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suggestion. I'd like to see the actual language you're suggesting.

MR. DAVID R. FINN: Well --

MS. ELAINE PATRICK: Is this a tobacco manufacturer of some type? I mean, I guess --

MR. DAVID R. FINN: Excuse me?

MS. ELAINE PATRICK: -- you could call it a tobacco manufacturer of some type, but are they're other tobacco processing or manufacturing around the state?

MR. DAVID R. FINN: Not that I'm aware of. There may well be, but --

MS. ELAINE PATRICK: (Voice too low to hear)

MR. DAVID R. FINN: I'm sure someone here would know. I was planning to submit a written, written comments and with it I could submit some proposed language.

MS. ELAINE PATRICK: Yeah, just draft what you have in mind, it's sort of hard to speculate. You can still mark the exhibit, when --

MR. DAVID R. FINN: Okay, any questions? All

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right.

MS. CAROLYN WEST: Call on Mr. Fader.

MR. IRA FADER: Good afternoon, Commissioner, Counsel.

COMMISSIONER KOELLEIN: Good afternoon, Mr. Fader, nice to see you, again.

MR. IRA FADER: Again, right.

COMMISSIONER KOELLEIN: You have something to do today?

MR. IRA FADER: Well, we'll see what we can pass on to the group.

COMMISSIONER KOELLEIN: Okay.

MR. IRA FADER: I am speaking here as President of my company, A. Fader and Son, it's a chain of tobacconists and needless to say I am opposed to the MOSH regulation on smoking in the workplace. I believe there are two issues to be looked at and discussed with regard to this proposed regulation.

First the regulation appears to be the result of the EPA directive that environmental tobacco smoke, ETS, is a class A carcinogen. However, one must bear

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in mind that the EPA has formulated a number of rather questionable risk assessments in the past. As an example, in the 1980's EPA forced scores of financially hardpressed school districts across the nation to remove asbestos, only to discover that asbestos is relatively harmless when left alone.

Example, in 1982 the residents of Times Beach Missouri, a town of 2400 people, were forcibly evacuated from their homes because of an EPA risk assessment that concluded that the community was contaminated by dioxin. Only years later, after the town's 800 families had endured the trauma of being dispossessed of their homes the EPA admitted that the concentration levels of dioxin at Times Beach were not harmful. These are but two examples. The other week or so there was an episode on television, John Stossel, which pointed in on a number of EPA risk assessments that were somewhat sloppy.

In 1990 the EPA's Science Advisory Board issued a draft report claiming that environmental tobacco smoke or passive smoking was a carcinogen.

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1990 that was. One year later the Board's own chairman, Dr. Morton Lippman, told reporters when questioned about ETS that the risk from ETS is, quote, "Probably much less than you took to get here through Washington traffic." A panel appointed by former EPA Administrator William Reilly admitted that many of its regulatory initiatives are on shaky scientific ground. It further acknowledged that EPA studies are frequently carried out without the benefit of peer review, quality assurance, and that EPA science is perceived by many people both inside and outside the agency to be adjusted to fit policy. And that I think is what we have here.

Two major studies that found no correlation, one of which from the National Cancer Institute, were either rejected or ignored and standard statistical procedures were flouted in the EPA's pronouncement.

A year ago a lawsuit brought by many in the tobacco industry challenged the EPA report on passive smoke. The suit alleges that the EPA manufactured scientific data, violated its own guidelines and

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overstepped its regulatory authority in conducting its risk assessment on ETS. According to the complaint the ETA used faulty science, improper scientific procedures to arrive at its conclusions. The complaint further states that the EPA ignored recent scientific studies, such as the National Cancer study, that contradicted the Agency's conclusions, and that the EPA used scientific assumptions and methodologies not generally accepted in the scientific community.

Unfortunately, as in most cases of this nature, it winds painfully through the court system. In the meantime, this Commission here, MOSH regulation, is imminent, and is being considered without regard to the decision of the Federal Court in this case. This afternoon my wife called me on the phone and said "Are you going to testify this afternoon," I said "Why yes," "Well I just heard on the radio that it's a fait accompli, that this regulation will be passed." I hope such is not the case.

Secondly, the other issue and even more important is the opportunity and ability of business in

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

this free state of ours to operate as management deems in its best interest. When approximately 30 percent of the adult population enjoys smoking it seems ludicrous to prohibit smoking in bars, taverns, restaurants, as well as other indoor areas that traditionally have accommodated smokers. If a restaurant wants to prohibit smoking so be it, that is a management decision. Conversely, if management's decision is to accommodate smokers they should be allowed to do so if they feel it is in their best interest and is the desire of their customers and in the best interest of their business.

I spoke to the owner of a small print shop the other day with four employees, the owner as well as all of his employees smoke. Are they to be denied the right to smoke? The wording in this proposal would even prohibit smoking in an individual's own home if a maid was working there or an electrician or other contractor was being used.

Where does the intrusion into personal rights by the government stop? Our economy has been built on

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the ingenuity and creativity of individuals to develop business. With excessive controls we stagnate and "Big Brother" takes over. Let business operate as business deems best. If employees, or customers, want to work in the environment that management has created they will do so. If they don't they will go elsewhere, but let management determine how business is to be run.

The letterhead of the Agency states "A regulator helping people." This proposal is not helping people, it is destroying business.

In the letter that I, the six copies I sent previously shows a study of the percentage of buildings in which a pollutant is a problem, and as you see from the high of 31 percent of pollutant which is an allergenic fungi, 29 percent dust particles, down down down, only 2 percent is tobacco smoke.

I trust that the Commission will do diligence and find that, what is in the proper interests of the people of Maryland.

COMMISSIONER KOELLEIN: Thank you, sir.

MR. IRA FADER: Any questions I can answer

Source: https://www.industrydocuments.ucsf.edu/docs/fjgl0000

for you? Thank you.

MS. CAROLYN WEST: Commissioner, Mr. Fader's testimony has been entered in as Exhibit 139.

(The document referred to as Exhibit 139 was marked for identification and received into evidence.)

MS. CAROLYN WEST: I now call on Dr., I'm going back and calling on Dr. Daniel Ford, who has arrived.

COMMISSIONER KOELLEIN: We're going to go off the record for five minutes to give this gentleman a chance to get set up.

(Off the record.)

(Back on the record.)

COMMISSIONER KOELLEIN: If we could go back on the record with Dr. Daniel Ford.

DR. DANIEL FORD: My name is Dr. Daniel Ford, and I'm a physician who graduated in 1978 and then finished an internal medicine residency at Johns Hopkins. After finishing the internal medicine

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residency I did an epidemiology training program at the National Institutes of Health which lasted for three years and led to my getting a Master's in public health in epidemiology at Johns Hopkins School of Public Health. I am currently assistant professor of medicine, epidemiology and health policy and management at Johns Hopkins Health Institutions, and we're interested in prevention guidelines, particularly as it applies to what you do with an individual patient. I direct several courses looking at how we assess risk and how we look at clinical epidemiology, or epidemiology specifically applied to an individual patient, and I would like to take this opportunity to sort of bring you through what we think about epidemiology, what it can do for us, what it can't, and try to put for yourself some, give you some perspective in terms of all the studies that you've heard to date. So I'm going to cover the basics of epidemiology, how epidemiology can be used to help make decisions, how we can attempt to assess causality and then using these principles how we might see exposure of passive smoke

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as a cause of heart disease. I'm going to limit myself to heart disease.

Basically epidemiology is using common sense to a large extent to help us make decisions, but being careful about the measurement that we use and the particular questions that we're trying to answer. And you, epidemiology is based on assessing risks and relative risk is the most common way of expressing this risk.

What you see here, we go through relative risk is the incidence or the new disease in exposed populations over the incidence of a new disease in a non-exposed population. Incidence means acquiring a new disease, so you would have started with no disease and then you get a new disease. Anyone in a calculation of instance that already has a disease, like heart disease, would be eliminated from those calculations. And I think, just to give you a feeling for it, if we took 100 people without heart disease 50 have diabetes, 50 do not have diabetes, of the 50 diabetics 20 get heart disease in the next 10 years, of

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the 50 non-diabetics 10 get heart disease in the next year, and you would have then a relative risk for a diabetic to get heart disease of about two. And that's how we calculate relative risk using many different studies.

In the bottom of this slide I have the range of relative risk calculations and how we generally try to interpret them. And you'll see that less than one you usually say there's a negative association between a risk factor and a disease, 1.1 to 2 is generally considered a weak association, 2 to 4 a moderate association and greater than 4 a strong association. Although I want to mention to you that in chronic disease epidemiology, and that's what we consider heart disease, a chronic disease, most of the relative risks, even for the risk factors that we're very confident on such as blood pressure and cholesterol, are in a range of 1.5 to 3. We rarely see relative risks of over 4 when we're talking about diseases that have multiple causes, such as heart disease.

There are several types of study designs we

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can use to assess the evidence to help us decide on whether there really is a causal relationship, and this gradation of strength of evidence you see here is being used by several groups to develop guidelines, to help us decide should we tell a physician to order a mammogram, should we tell a physician to look at cholesterol, and these are the order that we use from strongest to weakest, from analyzed clinical trials, cohort study, case control study and case series and the last being a case report. And I'm going to go through each of these in a little bit of detail to give you a feeling of how you should look at some of the studies that have been presented in the overview.

The randomized clinical trial is the one that we feel most comfortable with that, it compares two equivalent groups of persons randomly assigned to an exposure or to some type of intervention. And the advantages of this is that it control, the control and experimental group are equivalent, they have all of the same characteristics. It's easy to establish a cause and effect relationship and with randomized group

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control you can reduce the biases that can invade some of the other studies. The disadvantage is that in many cases it's unethical to, to expose someone to such an experiment. It's artificial in the sense that it's not what occurs in real life and when you have an artificial situation it changes the measurement and how people see exposures to some extent. And many individuals would not agree to participate in such a trial. In our particular case I don't believe that we could conduct a randomized clinical trial to see whether passive exposure to smoke causes heart disease. It's never been done for smoking, I don't think anyone would agree to be randomly assigned to exposure to passive smoking or not. The best we might be able to do would be to randomize work sites to having the smoking removed or not, but again I find it unlikely that that would occur, that anyone would agree to work in an environment where you can get every worker in a worksite to agree to allow their site to be randomized and then potentially be exposed to passive smoke for the number of years it would take to determine if there

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really was an effect, particularly since most Americans by polling seem to believe that exposure to passive smoking is detrimental.

The next type of study we can look at would be a cohort study, and that follows individuals through time who are initially free of disease but who are variably exposed to the substance of interest, in this case smoke. The advantages to this is that you have a less biased measurement of exposure; in other words in these type of studies you would be asking right now are you exposed to passive smoke or not and then you would follow them up to see whether they actually develop disease. It's easy in those situations to also understand a temporal sequence, what went first, and you can calculate rates. You can actually say of those that are exposed to this much smoke 10 per thousand will get such and such a disease. The disadvantages with this is, again, it's not like if we had randomized people, individuals still control -- you can't control for what they've been exposed to and certain individuals will choose to be in a non-exposed

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environment, others will by no choice of their own sometimes be exposed as well. And in these situations there's almost always more than one possible explanation for the results, you have got to decide when you see the evidence what's the best explanation, but it's difficult and there's some tricks or some of the procedures that we use to try to come up with what is the cause but there's always going to be some contention in any one particular study. And it requires a long period of time to complete so you have to say "Have you been exposed to smoke," and then maybe follow them up for 10, 10 or 15 years.

The next study which you probably heard about is a case control study and that's when you retrospectively compare the exposures to cases, people with disease, and controls, people without the disease. So that is let's find someone that has just had a heart attack and find out in the past have they been exposed to smoke or were they a smoker. The advantages of a study like this is that you can study relatively rare outcomes, like lung cancer which has been studied in

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this way, it's relatively in expensive and you can complete the study in a short period of time. You can just go find your cases and controls and, and measure their exposure in the past. You don't have to follow them up for years. The disadvantage is, of course, that the assessment of past exposure may be biased. Those that have just been told they had a heart attack or lung cancer or whatever may remember and report more exposures in the past because they're like all of us when we get a disease, they're trying to figure out what caused it. You, even in this type of study, cannot control for why an individual was exposed or not and for this it may be difficult to assess temporal sequence. For example if you were wanting to look at, say, does depression cause heart disease it would be difficult if someone had just had a heart attack to assess whether you may find high rates of depression but you wouldn't know whether it had come before or after the heart attack.

The next is the case series, and this is usually quite exploratory. This is in the beginning

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where you just describe a series of people with disease and look for the patterns of risk factors and exposures. It's very inexpensive although it's relatively new and that's why we call it exploratory. And the disadvantage to that, you cannot compare rates of exposures in cases to non-cases. We don't have any non-cases. And still the assessment of past exposure may be biased, and often these data are not really collected systematically. And the last would just be a case report just describing a single patient's disease and medical history and for the most part that's totally inadequate for us to try to decide on diseases where there are multiple causes.

Well, how do we assess the health impact of an exposure? And you will have a greater impact from an exposure if the, if that exposure is a very strong risk factor or if a large proportion of the population is exposed to it. And both of those are relatively independent but each can have a big impact on the overall health impact.

I want to go over just a couple examples for

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you that sort of bring home this point, although what I'm talking about is not really a substitute for Dr. Stewart's earlier quantitative analysis, but I think they're all fairly reasonable assumptions. And let's suppose that the relative risk for direct smoking causing heart disease was 2.0, and the relative risk for passive smoking causing heart disease was 1.2, a fairly small but still measurable risk. And let's assume that one smoker, direct smoker, leads to the exposure of two non-smokers, and then we'll take a population of 1,000 people and just run through what this means. If you see that would be, and I'm saying a rate of smoking of 25 percent of the population which is a little bit lower than what we have but fairly close to what we project in the next year or two, you would see the relative risk for heart disease in those smokers was 2.0, the rate would be 20 per hundred and you would have 50 cases of heart disease. The exposed non-smokers would be a larger group, that would be 500 people, and even though the relative risk would only be 1.2 and a very small rate of 12 per hundred the overall

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number of cases there would be 60. And then if you look at the people that are not exposed in any way they have a relative risk of one or at a baseline, their rate would be 10 per 100 and they would only have 25 cases. So you see, even though it's a small risk of 1.2 the number of people exposed leads to more cases in the exposed non-smokers than those that are smoking directly.

Now let's look at the next example. Let's take another situation where we have a factor X which is a very strong risk factor for heart disease, 10 times the risk, but the exposure to that factor X only occurs in three percent of the population, like if there was a toxin in their work environment or something like that. The rate of heart disease again being 10 per hundred in a population of 1,000, and you see that of the 30 that there'd only be 30 people out of 1,000 that would be exposed to this factor X, they would all be very prone to heart disease; in fact all of them would get heart disease in this case. Yet if you look there that's only 30 cases that would have

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occurred, and if you remember back to the last example there were 60 cases caused by that exposure to passive smoke.

So to summarize, an exposure with a small relative risk but present for a large population can cause a significant amount of heart disease.

This is another relatively confusing area that's difficult for someone who hasn't been exposed to these concepts all the time to understand. We have difficulty with medical students and new public health students with these concepts as well. But it's the question of confidence intervals, and we see that all the time now. In science the goal is generally not to prove there is an association but to disprove that there's not an association. Because it's very difficult to prove anything completely in, in the biological sciences. And the confidence intervals will indicate how confident you should be about your results. In this case if you saw the relative risk was 1.3 with a confidence interval of 1.1 to 1.7 the way to interpret that is that the relative risk of 1.3, the

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best estimate of the association, with this study the estimate of association could be below 1.1 or above 1.7 in 5 percent of the instances when this study was repeated. Another way to say this is if the study is unbiased there's a 95 percent change that the interval, 1.1 to 1.7 includes the true effect size. The larger the study the narrower the confidence interval and the more certain one can be about the size of the true effects. I think we can probably think of similar analogies in the, in baseball or some other sports where we look at numbers and we can try to determine how much confidence we have; for example in the month of May when hitters only had a limited number of bats we may not be as confident in the batting average as when we would be by the end of the season when they've had four or 500 at bats.

I want to show you this, and I think you can refer to the figure if you can't read the slide well. It's some interpret confidence intervals, it says the probability of the true estimate is the same within the entire confidence interval, and that isn't true. If

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you look, and it's a little bit difficult without a pointer, but you see with that arrow down there we have a relative risk in this particular case of 1.27, very close to what we think with heart disease, and the 95 percent confidence interval is .67 to 2.44, and that's why you see the very broad band. But it is not an equal probability within that entire confidence interval. The probability of the true effect is much closer to that relative risk of 1.27 than it is to the ends, so that even when you have a broad relative risk don't think that the true probability or that the probability of the true effect size is just as equal on the ends as it is in the middle, because the middle is where most of the, the highest probability that that's the true estimate will occur is.

Let me just mention a little bit about confounding. You may have heard that mentioned before, and that, I want to go through an example with that. If we say in a study have we identified the direct cause of disease or another factor only indirectly associated with the disease, and again this is always

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of a concern in an observational study. For example, factor A may cause disease X but then we have another measure of factor B, and factor B is a confounder. If it's a risk factor for disease X and it's associated with factor A but not directly the result of exposure to factor A. And let me show you a result that may, an example that might bring this point more clearly. If we say smoking is a risk factor for heart disease the potential confounders that may actually impact on that relationship might include lack of exercise, low vitamin intake, personality factors. All of those could be related to smoking and also related to heart disease, and the question would be well which of those exactly is the cause. From a policy point of view sometimes confounding is not as important though as it seems, because for example if patients who stop smoking exercise more because they breathe easier then that, it's beneficial to reduce that smoking regardless of which factor was most directly related to the heart disease.

What are some of the difficulties we always

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have in determining causation and observational epidemiological studies? One is the assessment of the exposure. You can imagine if we take passive exposure to tobacco smoke, I feel that's one of the most difficult factors to measure, and that impacts on why we have a problem in finding or being able to have much confidence in our findings. That is because passive exposure can occur in many different sites, the person is not even directly reporting on their own behavior, they have to report on the behavior of people around them, and it varies, it may vary a lot over the lifetime of an individual, and that impacts on the duration of exposure that can occur. For the assessment of outcomes we would always like to have a blind observer assign the outcomes, that they don't know what the exposure was of that person. That's less of a problem for passive exposure because if someone was reading a death certificate or a hospital record it would be unlikely that they would know whether that person had ever been exposed to passive tobacco in the workplace or at home. That doesn't occur in most

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clinical records, that data. So I think for most of these studies we can assume that there has been a blinded observer who is making the judgement about outcomes. And we also want complete assessment of all people, that's, again, another challenge. We don't want to have people drop out of the study.

The assessment of confounders, we want to hope that we've identified the main confounders and measured them with enough accuracy to say we've really controlled for those confounders. And, again, it's often a problem that we may have some measure of the confounder but it isn't measured a accurately as the main exposure variable we're interested in. And that can lead to some difficulty in interpreting the results.

Well now let's look at our review of recent studies that are directly relevant to this issue. And I know you can't read that, that's why I've given you the handout, but I wanted to say that this came directly from a summary of studies in circulation. And if you look here there's been, all of the studies

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listed up until 1991 there have been three case control studies reported since then which I think essentially show more or less the same results, with a risk factor somewhere between .9 up to 1.85 in terms of the risk of exposure to passive smoke and heart disease. But if you look down the relative risk column there you see what I would consider a very marked consistency in the reports. The relative risk we see 1.3, 1.2, 2.1, 1.3, all of the risks being above 1 except for the one study which was 0.9. Now if you look at the confidence interval, because many of the studies have been relatively small there is a wide range of the potential estimate within those confidence intervals, and some of them do include 1 which would be a calculation which would suggest there was no direct association between the two. But if you look at the bottom there, something called the pooled estimate which attempts to combine the studies and is being used very frequently now as a technique as we begin to try to make policy statements, you see that the pool estimate would suggest a relative risk of 1.3 or a 30 percent higher

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risk than non-smokers for those that had, were non-smokers and had been exposed to passive smoke.

The results show that the, you see that pretty much the same results in different countries for both sexes and all of that gives us confidence in the findings.

I want to highlight two studies for you, both done in the United States, which I think can also give you some feeling of, of where the data lies. This is the table from the, the Washington County study by Helsing that you may have heard about, let me just run through it a little bit for you. In 1963 there was a census done or an interview of a large number of homes in Washington County, so this data, Washington County in our own State of Maryland. This data then for the most part should only be generalized to the white population. In 1963 they assessed sex, age, race, marital status, years of schooling, housing characteristics, smoking behavior of everyone in the household, and then from 1963 to '75 they read all the death certificates in terms of, to determine if they

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were related to ischemic heart disease or coronary artery disease, and then they calculated rates; for those people who had exposure to tobacco in the home were they more likely to have died of heart disease. This is the largest study that we have so far and has relatively small confidence intervals. And if you look just at that first column, the passive smoking score, just compare those with the 0 to 1+, you see that the relative risk for men was 1.31 and the estimate could range anywhere from 1.1 to 1.6. It's very reassuring to see that there's almost the same relative risk for women, 1.24 with a confidence interval of going from 1.1 to 1.4, and I think if you look down through all of the age groups for men you see for the 25 to 44, the 45 to 54, all of the age groups, that those who have more exposure to passive smoke at home had a higher risk of dying of heart disease. The same thing is shown in women. The one age group where the data is fairly flat or there's not a clear demonstration of relative risk is for women in the 55 to 64 year old range. Nonetheless, it is shown in both genders and over most

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age groups.

Now I don't think, if this were the only study we would have some concern because it's one estimate and although it's a very large study it, they did not have data on some of the risk factors that we know have a strong association with heart disease, such as cholesterol and blood pressure, and we would want to see in some other studies if they've looked at that. I want to then highlight for you the next study which was conducted from 1973 to 1982, and this is a very detailed study and this is often the choice we have to make in epidemiology; do we do a large study that has fairly limited assessment of all the risk factors or go with a small study that gives us very detailed information on each participant. This is the detailed study and it follows 1400 men who had never smoked for 9 years and tried to determine if having a wife that smoked was an independent risk factor for heart disease. And at baseline they measured almost all of the, they measured each and every one of the well known cardiovascular risk factors, so they had blood pressure

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multiple measurements, they had cholesterol including high density lipoproteins and low density lipoproteins, they had weight, alcohol, education, income, and they also measured biocytin in the blood so they could determine that none of these men that said they were non-smokers really smoked, and this eliminates this misclassification error that has been discussed. And they also followed up these people with periodic visits and they would be submitted to a carbon monoxide monitor to be sure that they had never, had not started smoking sometime during the study. So we can feel fairly confident that these people were not exposed to any direct smoke and only to the indirect smoke at home.

In addition this is a well known study that had the best methodology, all events were carefully assessed by multiple blind observers, they did not just accept death certificates they would look at hospital records, lab tests to assess the particular outcomes. And what you see there is for coronary heart disease death the adjusted rate of being was 1.59, that those

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men that had a wife that smoked at home had a 60 percent higher chance of dying of heart disease or having an event for heart disease. This same thing was found for death from any cause with slightly higher estimates, and although the confidence interval certainly includes 1 that's what we would expect. In a very detailed study we do not have a number of events to have a very small confidence interval but we can feel very good about the point estimate or that 1.59 adjusted risk, that that takes care of most of the identified confounders that have been suggested as other reasons for this relationship.

Well I want to just go over briefly some of the criteria that we use to assess causality and then see how it applies to this particular case. We usually want to look at the strength of the association, whether a dose/response relationship is apparent between exposure and outcomes, the consistency of the association across multiple studies, whether it is a temporal relationship, did the exposure clearly come before the event, what's the effect of removing the

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exposure, the specificity of the relationship between the exposure and the outcome, the biological plausibility and to what extent have alternate explanations been adequately considered and excluded.

Now I gave these a grade for how I attempted to see these criteria for this association, and again I came to this with some interest in the issue of passive ETS but I had never looked at the data in depth until the past several weeks, and I applied the methodology that's been used by the US Preventive Services Task Force to come up with recommendations for preventive care that we would incorporate in patient care. I want to emphasize to you that when, the grading that I use, A B and C, A means there's definite evidence, B means there's good evidence, C means there's no evidence one way or another, it does not mean what I would say E, that the evidence is against it. So C means there's really no evidence, no data to help us make a judgement one way or another.

Well let's look at the first one, the strength of the association. The association, the

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summary risk that we found has been between 1.2 and 1.3. I agree that's a fairly modest association in terms of it's strength, but again to put it in perspective most heart disease risk factors have risks of around 2, so for blood pressure, cholesterol, it's somewhere between 1.5 and 2.5, and even direct smoking and heart disease is going to be a relative risk around 2. And even small effects and small associations can enlarge effects when applied to a large number of the population. The dose response relationship I then gave a B because it's somewhat inconsistent, you see it in some studies and not in others. This does not bother me too much because I think the measurement of passive exposure is so difficult and prone to error that it would be very difficult to demonstrate a clear dose/response relationship in this case. I think you have very consistent point estimates and for that I gave it an A. It's again shown in men, women, multiple countries, young and old. This is marked consistency for what we have found in several other situations where we're trying to look at an assessment of an

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exposure and a disease.

The temporal relationship I grade as an A; it's quite easy in this case, we know that the passive exposure has occurred before the, the heart disease. And I think this is fairly easy and clear to make that judgement.

For removing the exposure I gave it a C which means there's no data. We really don't have the -- it'd be nice if we could acquire the same data we have for smokers, we know when smokers directly, the direct smokers stop smoking their relative risk of heart disease gradually goes down over the years, and again we just do not have that data for, for exposure to smoke in the workplace or home, and I'm not confident that we'll be able to get that data soon because you're going to have to have a very large number of people in this study to be able to assess any change in this very small level of risk.

Specificity of the relationship, I gave that a B. I don't know, this is a criteria that has more of a relationship to infectious disease than it does to

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chronic disease. Yes, tobacco smoking does not just cause heart disease, it causes many other diseases, but again blood pressure doesn't just cause heart disease, elevated blood pressure causes stroke and renal disease, and it's very hard in most chronic diseases to really get a convincing role for the specificity of the relationship. For biological plausibility I graded this as an A, I think we have, if you look here this is one of the graphs that has been developed, a figure to help us show how tobacco smoke causes heart disease, the exact mechanism is not known, the consistency of the effect and the persistence of the effect is clear. It can, we think that tobacco smoking can have its impact on heart disease primarily through either carbon monoxide or through nicotine, and we have clear evidence that either of these can have an impact on heart rate, blood pressure, platelet effect which is, which platelets look at the ability or affect the ability of clotting to occur in the coronary arteries and can cause an impact on heart disease either right within a short term or in a long term. So I think that

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although the reported effects are higher than what we might expect if we just did a straight relationship of the dose of passive exposure to direct smoking there may be differences in how the exposures occur and what impact that has on the cardiovascular system. For example, we know that acute effects of nicotine are different than chronic, and someone that is smoking every day, the direct smoker is going to have nicotine in their system probably from the age of when they start smoking until they stop, so from 15 to 65 for example they may have nicotine in their system every minute of their existence. For, to passive exposure to smoke it might be quite different, a person might for the weekend go home and have no effect from nicotine and then every Monday or every time they go back to work be submitted to the acute effects of nicotine at low levels and that may account for some of the differences in the effects of passive smoking and direct smoking, and some of the intermittent variables.

And then the last question is alternative explanations. Do we have other explanations for how

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passive smoking might be causing the elevated risk of heart disease that has been observed. I think with, in any disease where there's multiple factors involved there could, there is the possibility of confounding. I think most of the assertions that there's misreporting of smoking could not account for the fact, and in fact if you look at, for example, very carefully in that Mr. Pitt, the second study that I showed, the blood pressure, the cholesterol levels of those exposed to smoke and not exposed to smoke were almost identical, so that it hasn't been very clear to me what intervening factor has -- there's been many submitted, none of them proven that would account for the association that we've seen in these studies between passive exposure to smoke and heart disease.

I think to put this in perspective, that epidemiology is never completed and all scientific work is incomplete whether it's observational or experimental, and that we need to make rulings with the data we have at the time. There have been several authors individually who have suggested that the data

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does not show that there's a, a risk between passive exposure to smoke and heart disease. There have been no groups that have asserted that, and that the American Heart Association Council on Cardiopulmonary and Critical Care has concluded that environmental tobacco smoke is a major preventable cause of cardiovascular disease in men, and I think it's much, I would put more weight on what you see from respective groups whose reputation is at stake than you might see from reviews and individual authors.

Overall, as you compare this to some other situations I think there is actually a fairly large body of data that helps us make decisions in this regard. And the US has had a dramatic decline in heart disease and smoking that I think, that may, part of that may account for some differences that we've seen in the passive exposure to smoke as well.

So I would have the following three conclusions for you as you try to decide on this: That intervening to reduce exposure should be based more on the number of lives saved than on the level of risk;

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that a small level of risk applied to a large percentage of the population can have a big impact; and it's the number of lives saved that's more important. The relatively low level of risk associated with passive exposure and tobacco smoke is important because of a large number of individuals exposed, and the decision to limit passive exposure from tobacco smoke is easier, that is it is an easier decision to make than many others because there's no known benefits of tobacco smoke. In our situation when we're trying to decide should we tell a person, a young woman to have a mammogram, should we tell them to undergo a test or whatever, an intervention that has some risk of its own it's a much more difficult situation I think to come to a decision. In these cases there's very little balancing the risk, the potential risk of passive exposure I don't see in terms of health, and I'm strictly talking about health, I'm not talking about the loss of autonomy that can occur to individuals or potential economic consequences, but in terms of health concerns I think this is a relatively easy decision to

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make, that eliminating passive exposure to smoke would reduce the number of heart disease cases that we see in Maryland.

As a physician dealing with patients which is what I do to a large extent we're always trying to decide what's the best advice to give with low levels of risk, and I think this situation is very equivalent to telling a patient to begin exercising when they don't exercise, to decrease their salt intake in their diet so they don't get, have a risk of blood pressure, and I would put it in the same range of risks as what you would see in those conditions and in my view I would not want to be responsible for the non-smokers who get heart disease or cancer because I said that there was not an association from the data that we see right now between passive exposure to smoke and heart disease. Thank you.

COMMISSIONER KOELLEIN: Thank you, sir.

MS. ELAINE PATRICK: Doctor, I just have a couple of quick questions. You had a mix of grades in your causality which I take because factors that were

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shown go beyond epidemiology because they include a biological plausibility and that. Is it common to have that mix of evidence leading you when you're trying to make this judgement?

DR. DANIEL FORD: Sure, I mean that's why, we see them because that's why you had to develop all of these multiple criteria, criterion, because if we could just focus on one criteria that would be easier to show the, that there was a cause between exposure X and disease, and subsequent disease. The reason why they developed this list of eight is because in many situations you don't have the, the data, always the exact data that you would want and then always those involve some judgement of how, how good the evidence is on one criteria versus another, and you look at the total sum from all the criterion.

MS. ELAINE PATRICK: And overall your analysis of the literature leads to you the conclusions there's about a 1.2 or a 1.3 increase in relative risk to passive, lifetime of passive exposure?

DR. DANIEL FORD: That's right, from

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published studies that would be what I would think the best estimate of the risk of passive exposure to smoke and heart disease.

MS. ELAINE PATRICK: Thank you.

COMMISSIONER KOELLEIN: Thank you, sir.

MS. CAROLYN WEST: Commissioner, Dr. Ford's presentation has been marked as Exhibit 140.

(The document referred to as Exhibit 140 was marked for identification and received into evidence.)

MS. CAROLYN WEST: And I now call Richard Downin.

COMMISSIONER KOELLEIN: Good afternoon.

MR. RICHARD DOWNIN: My name is Richard Downin, I am Vice President of Washington County Club Association. On behalf of the clubs and fraternal organizations of Washington County we would like to go on record as opposing the prohibition of smoking in an enclosed workplace, especially the bar and club surroundings. We feel it would have a direct negative

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economic impact. On the average, better than 50 percent of the club customers are smokers, if we lose just half of these smoking customers we'll have a definite impact on employees due to loss of gratuities and loss of revenue to the organization which in turn could create lay-offs.

We also feel we would lose a substantial amount of business to the same organizations in our neighboring states due to the close proximity of the state borders. This would directly create a loss of income to the State of Maryland.

When researching just one specific Maryland club the records indicated that in the first quarter of 1994 we sold 1549 packs of cigarettes bought from a cigarette machine at an inflated price, which indicates to us that our customers choose to enjoy this legal product in a social environment.

On a personal note, as a non-smoker, I find it inconceivable that a state which cannot control its overwhelming problem with illegal substances is channeling so much time and money into trying to

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